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(54) **PROSTHETIC VALVES FORMED WITH ISOTROPIC FILTER SCREEN LEAFLETS**

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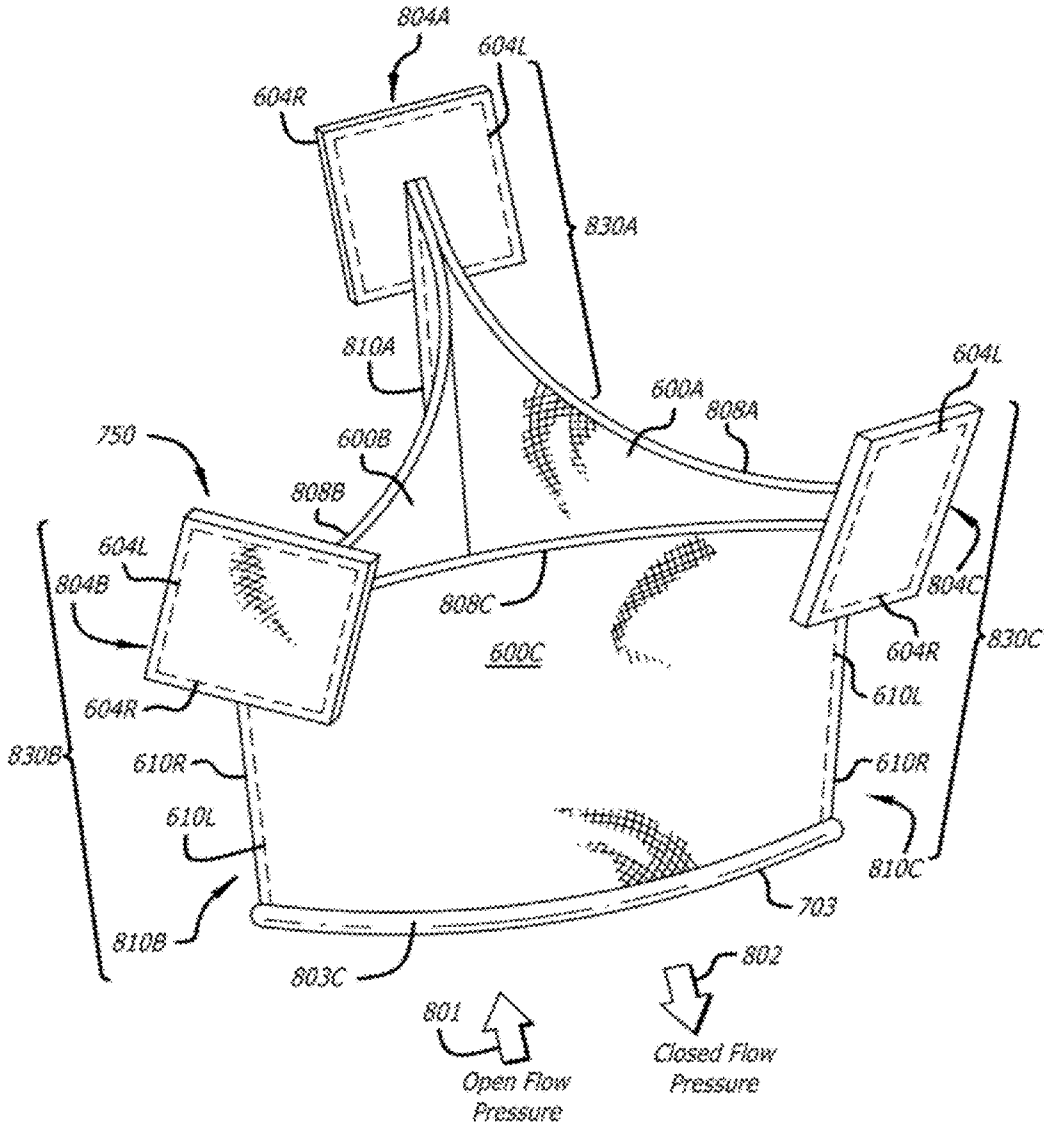
A61F 2/24 (2006.01)

(52) **U.S. Cl.** **623/2.12**

(57) **ABSTRACT**

"In one embodiment of the invention, a prosthetic check valve is disclosed with leaflets cut from filtration screen material with uniform pore size having openings with a dimension inclusively between fifteen and sixty microns. The screen material is made from biocompatible material, such as polyester or polypropylene. One or more outer edges of the leaflet are fused or sealed to prevent fraying of the material and to form a more non-thrombogenic surface. Prosthetic check valves assembled with the leaflets can be collapsed to a diameter of less than or equal to twenty-nine french (29*f*), sterilized, and stored in a collapsed state. The collapsed valve can be implanted without prior rinsing to remove sterilant.



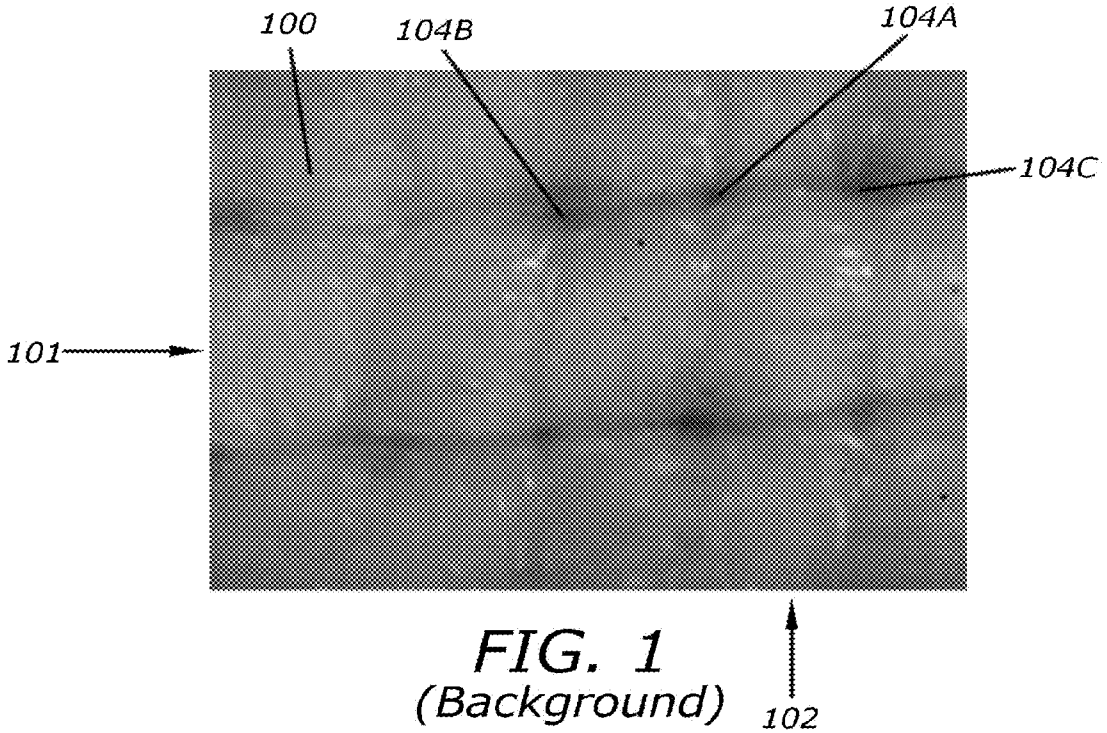


FIG. 1
(Background)

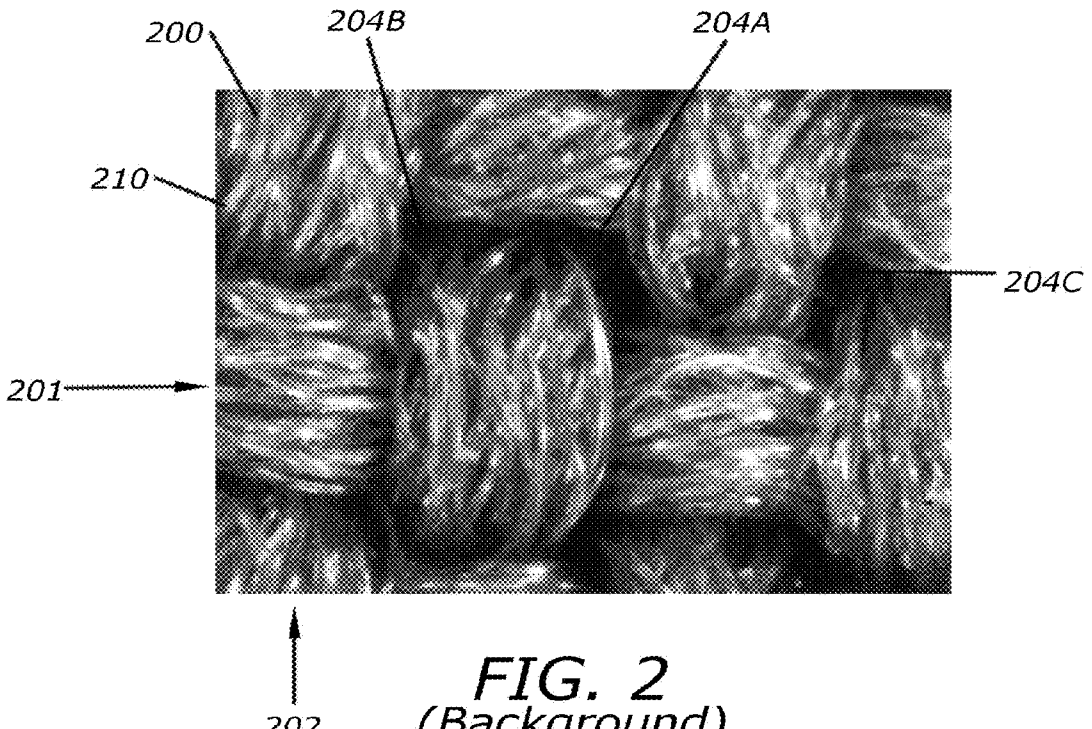


FIG. 2
(Background)

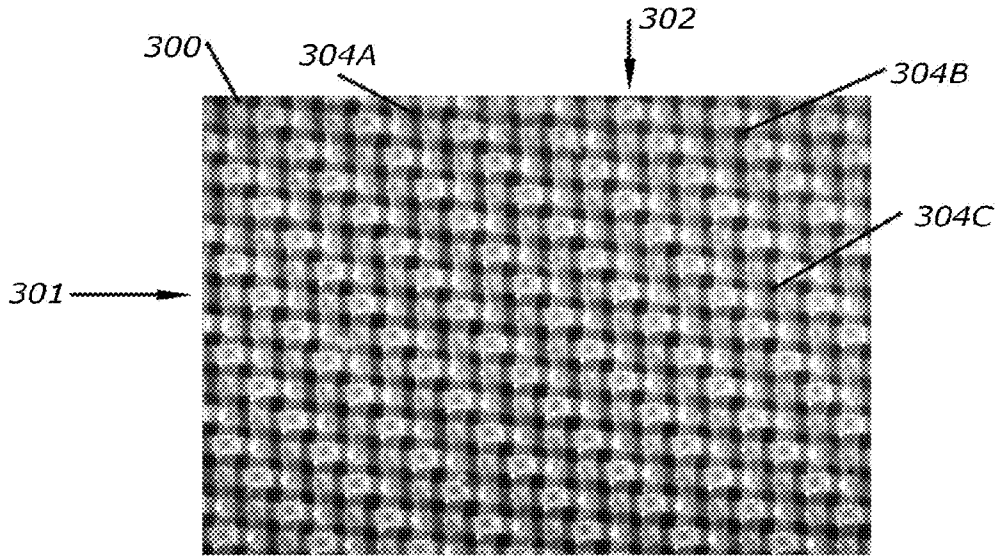


FIG. 3

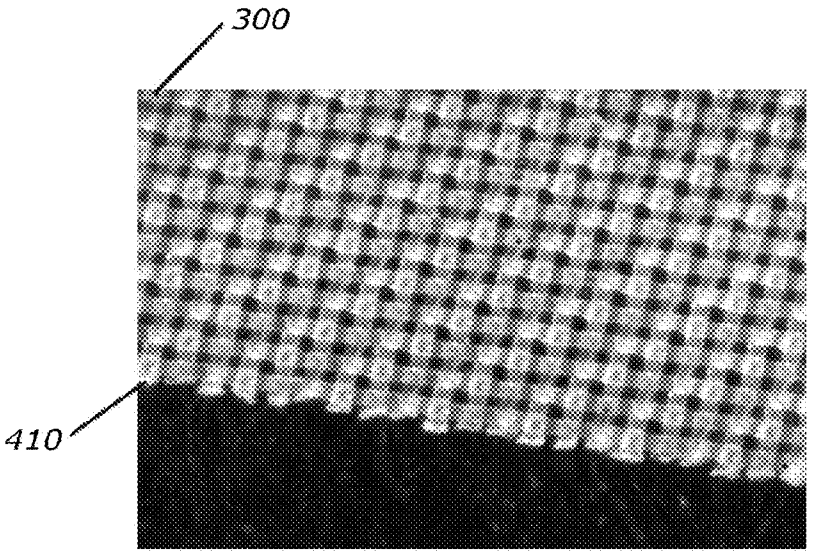


FIG. 4A

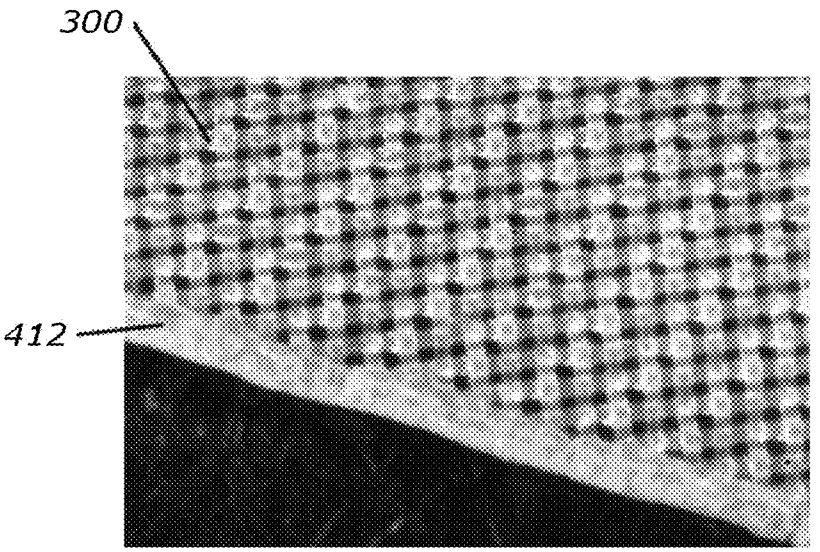


FIG. 4B

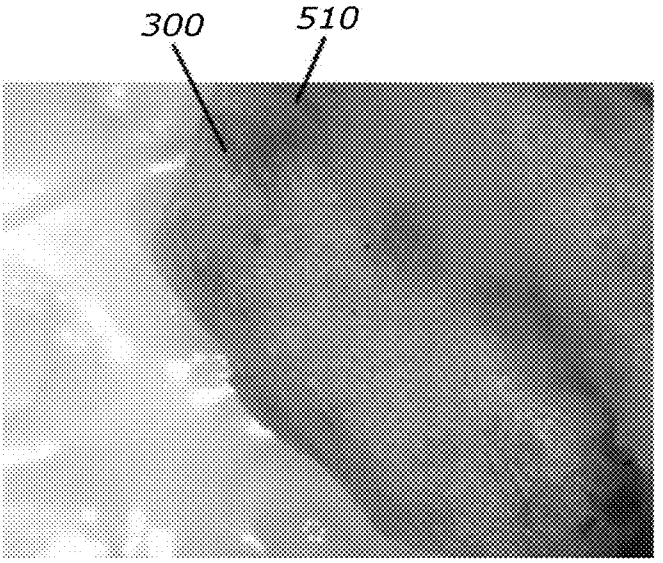
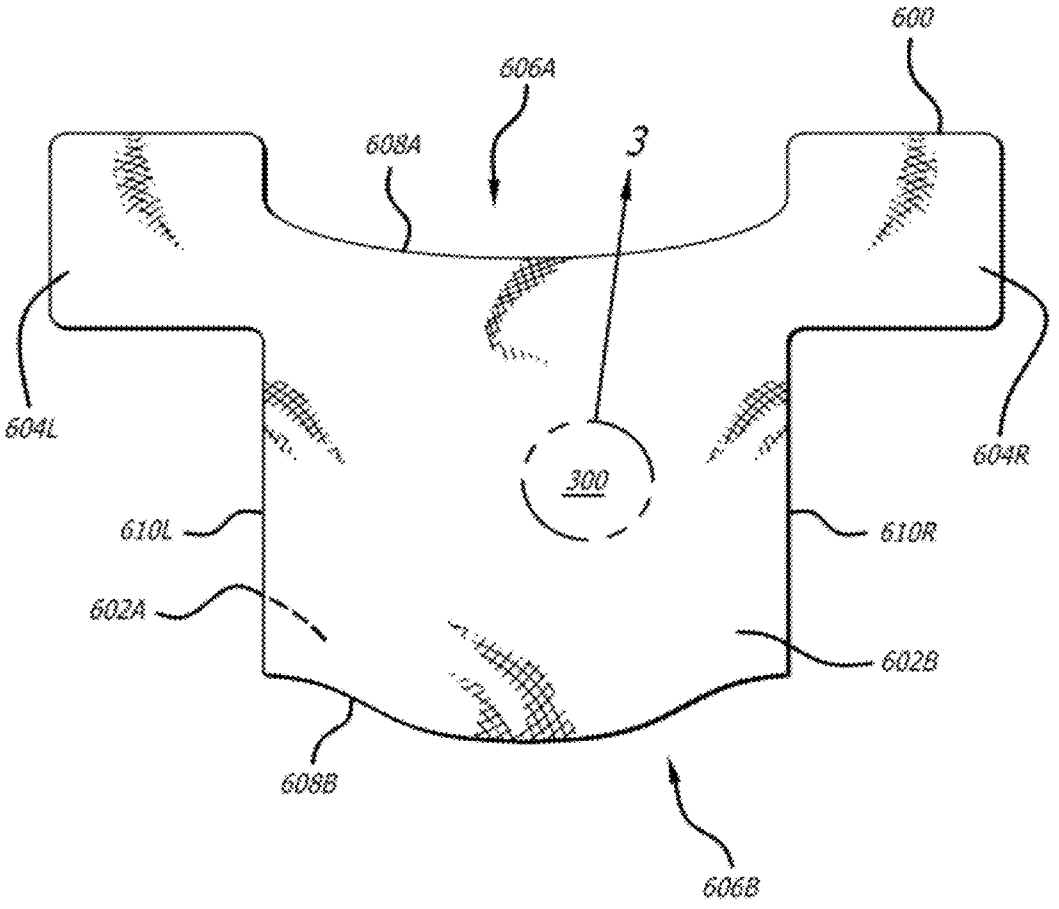


FIG. 5

FIG. 6



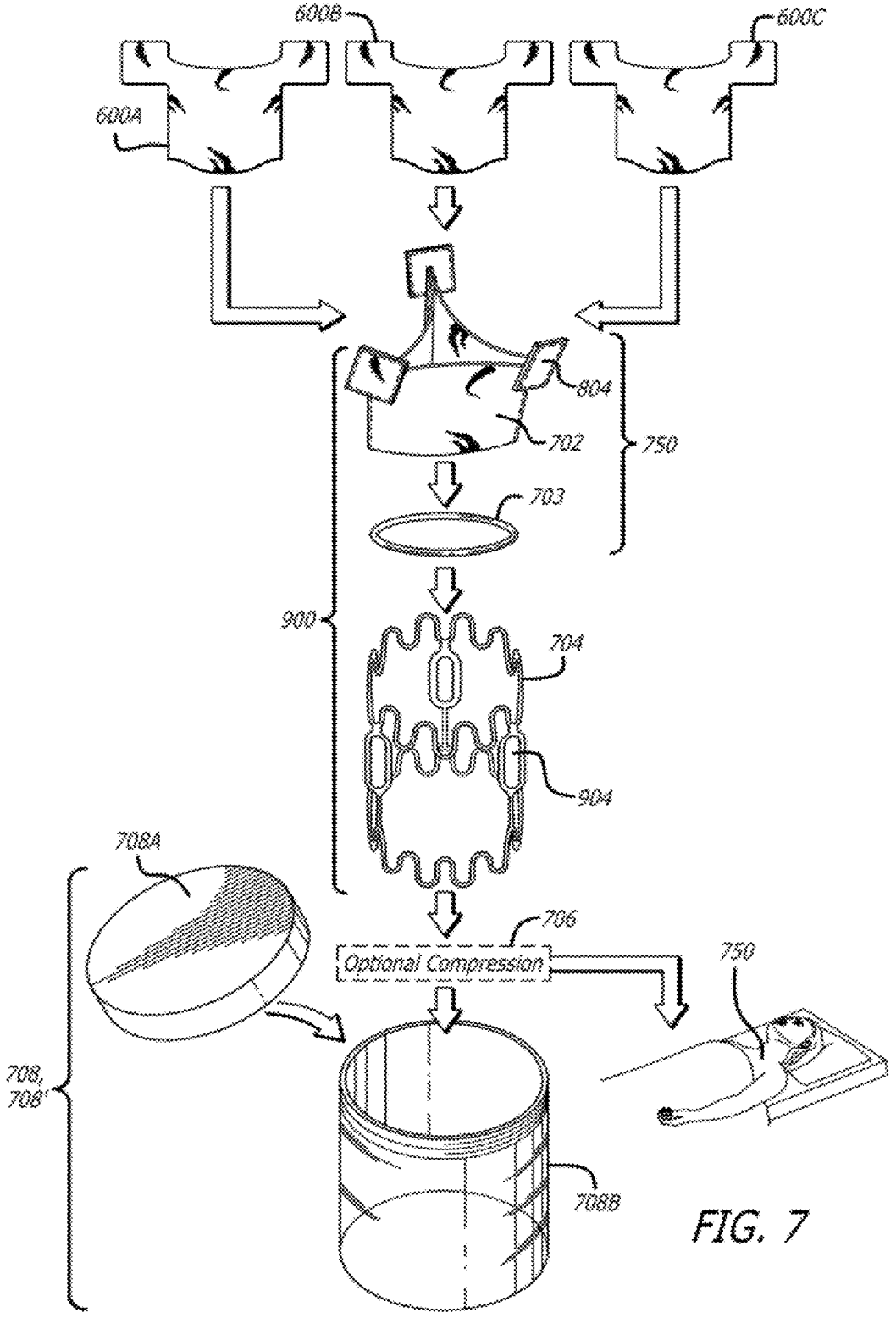
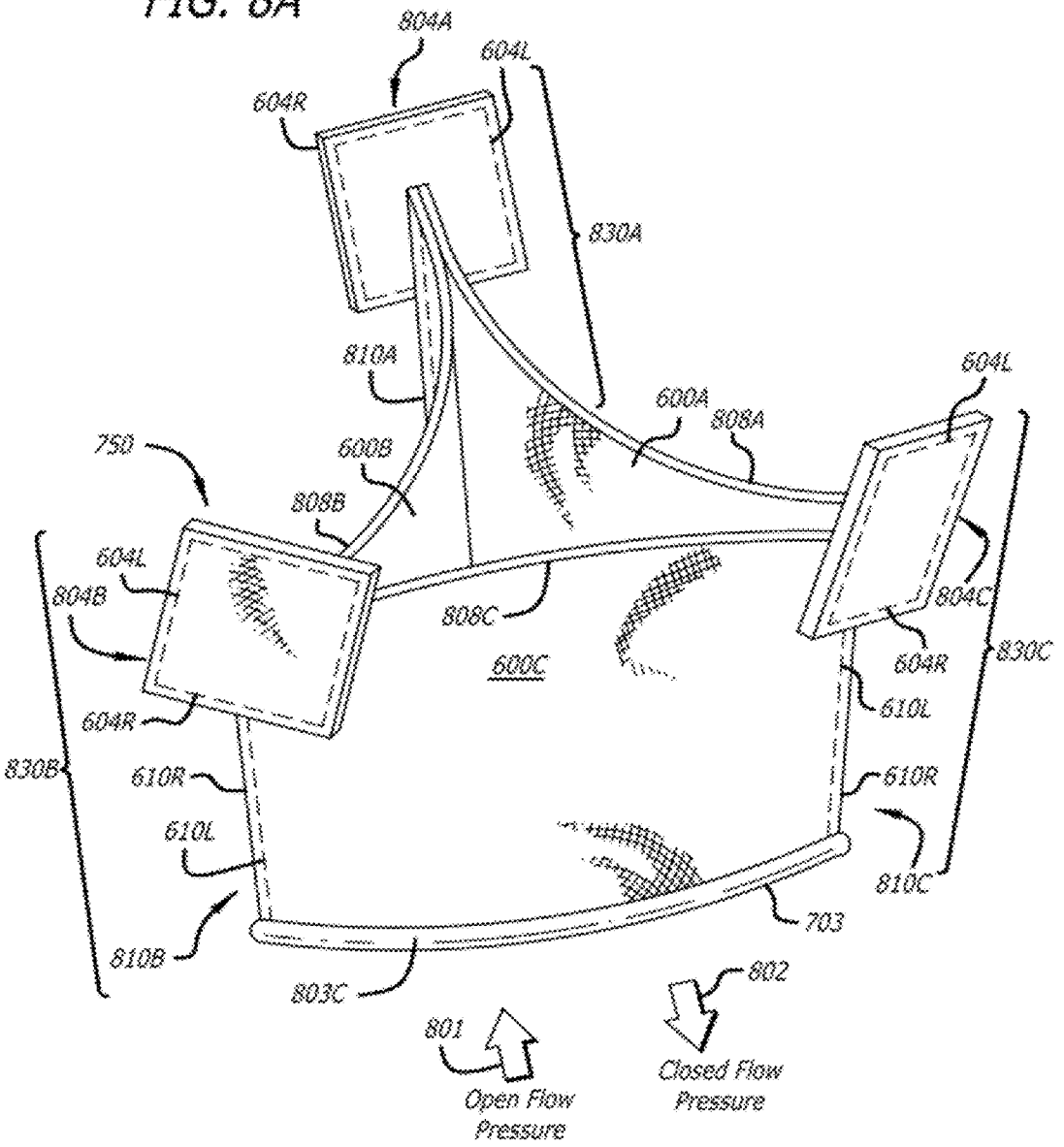

600B
600C
600A
804
702
750
703
900
704
904
708A
706
Optional Compression
750
708,
708'
708B

FIG. 7

FIG. 8A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604L
604R
830A
810A
600A
808A
604L
750
600B
808B
604L
804B
808C
804C
600C
604R
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610R
610L
810C
810B
703
803C
802
801
Open Flow Pressure
Closed Flow Pressure

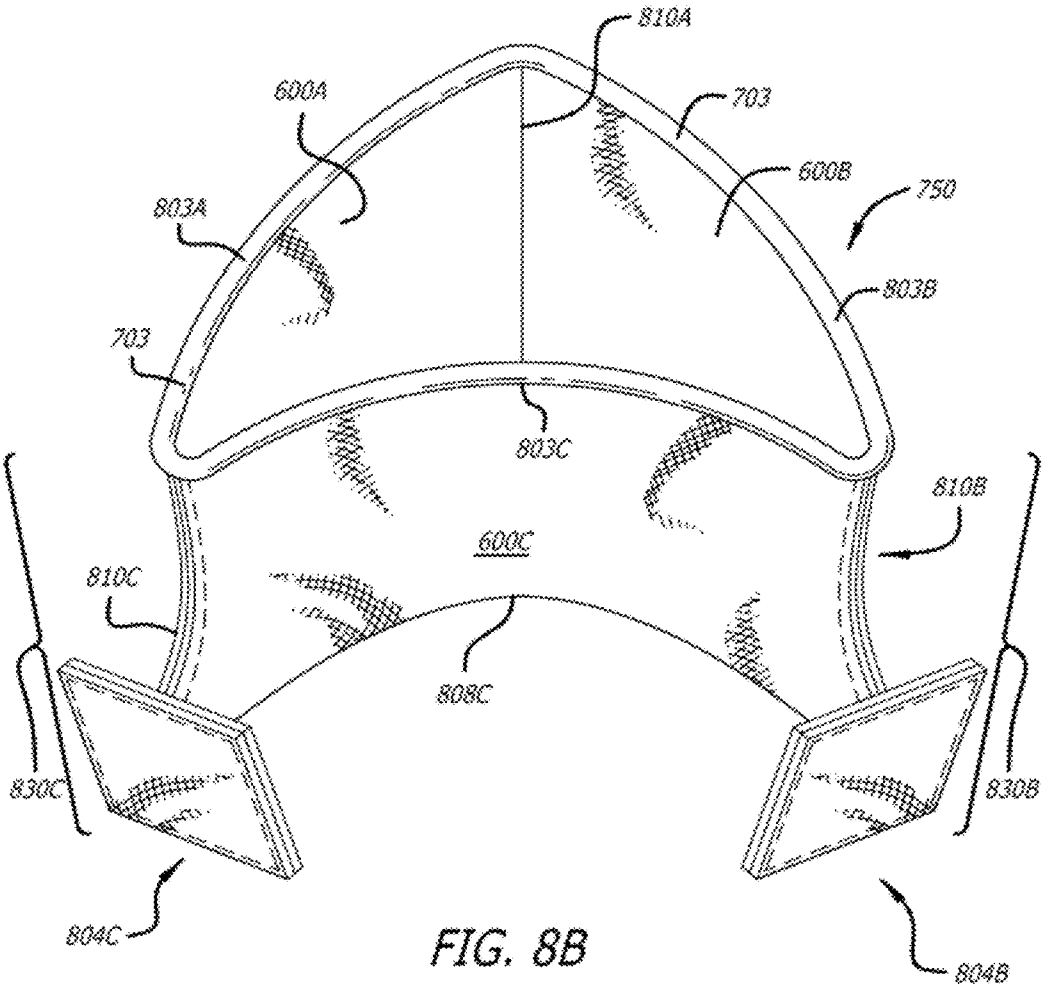

810A
600A
703
600B
750
803A
803B
703
803C
810B
600C
810C
808C
830C
830B
804C
804B

FIG. 8B

FIG. 9A

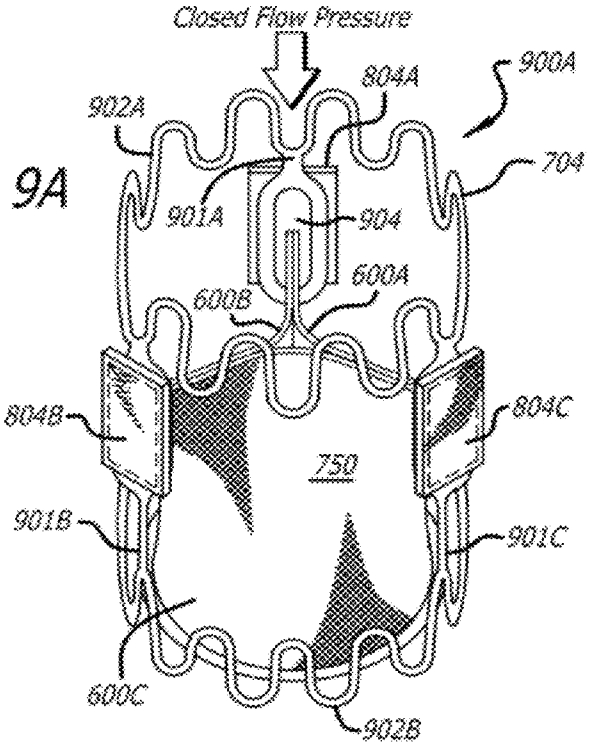
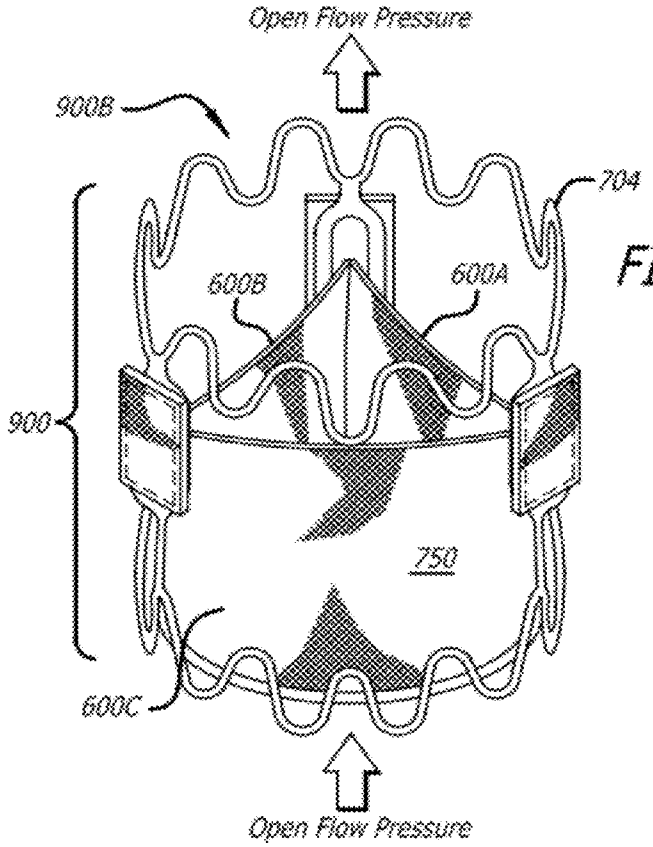

Closed Flow Pressure
900A
804A
902A
704
901A
904
600A
600B
804B
804C
750
901B
901C
600C
902B

FIG. 9B


Open Flow Pressure
900B
704
600B
600A
900
750
600C
Open Flow Pressure

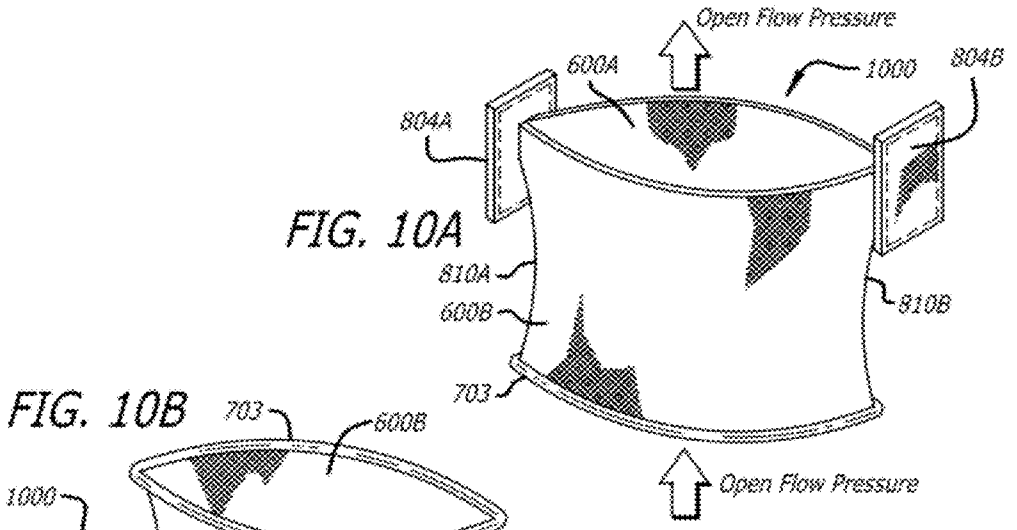


FIG. 10A

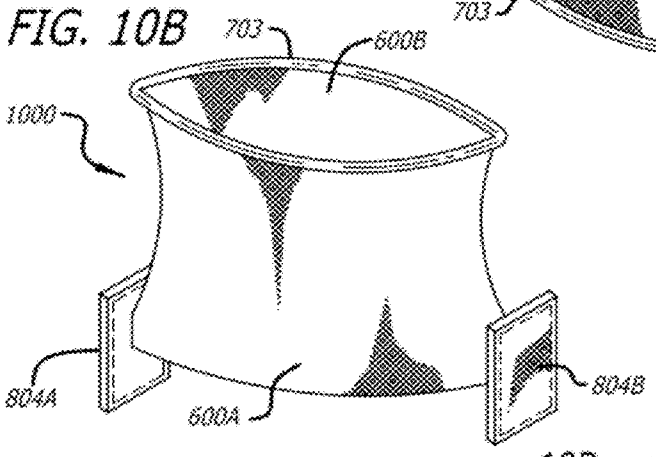


FIG. 10B

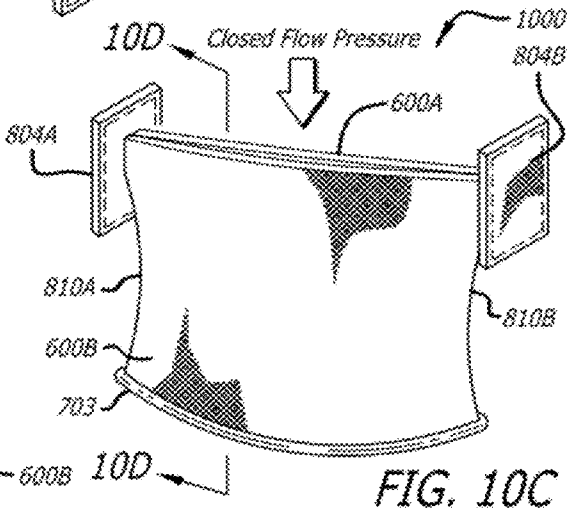


FIG. 10C

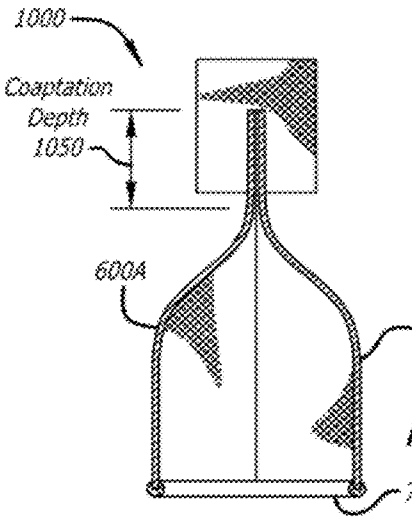
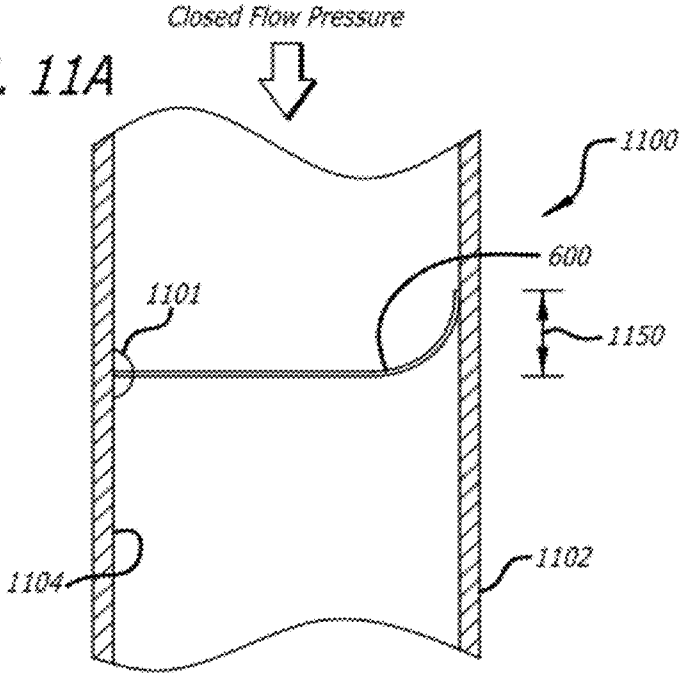


FIG. 10D

FIG. 11A



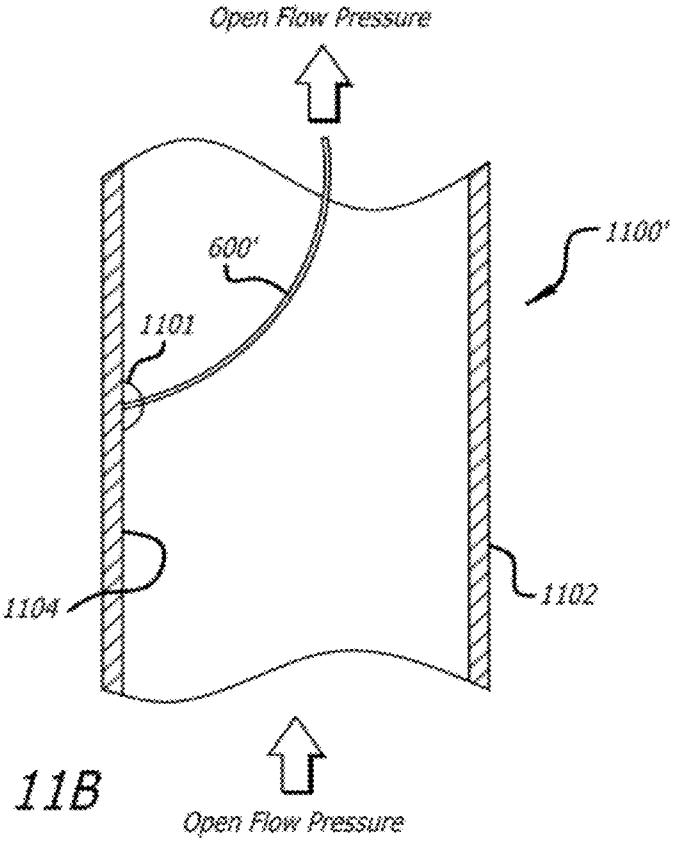


FIG. 11B

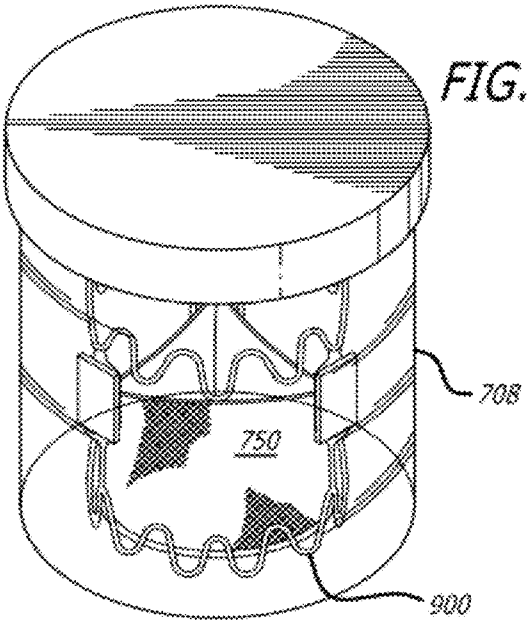


FIG. 12

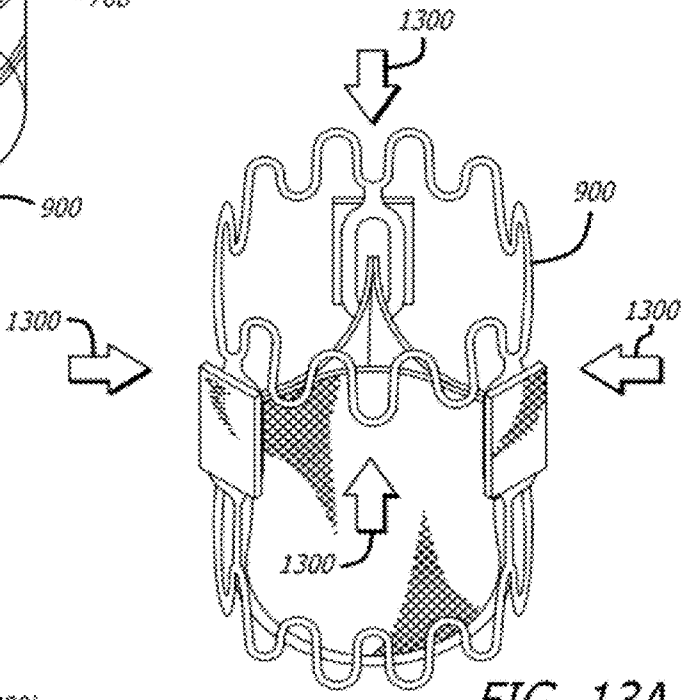


FIG. 13A

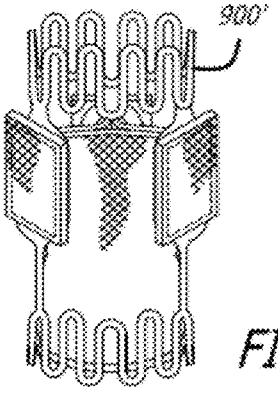


FIG. 13B

FIG. 13C

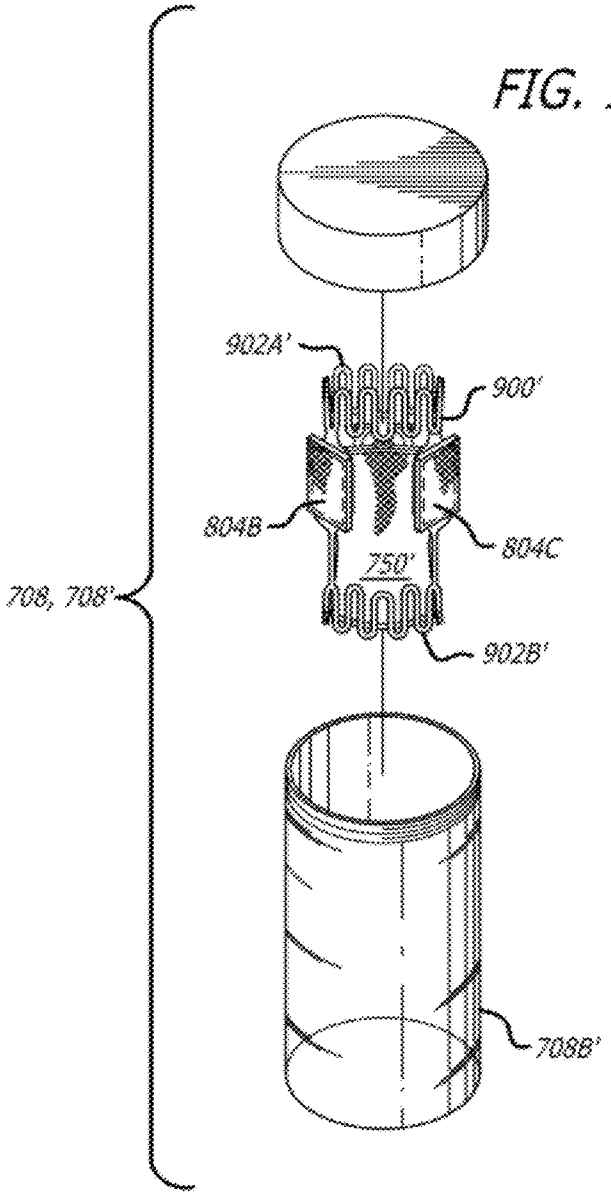
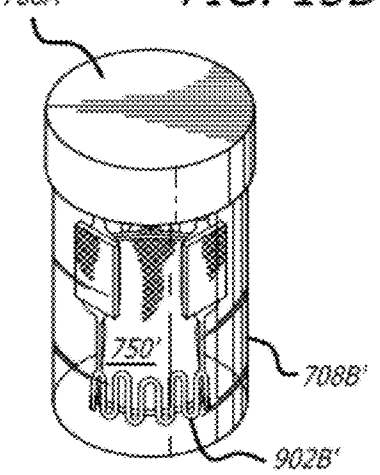


FIG. 13D



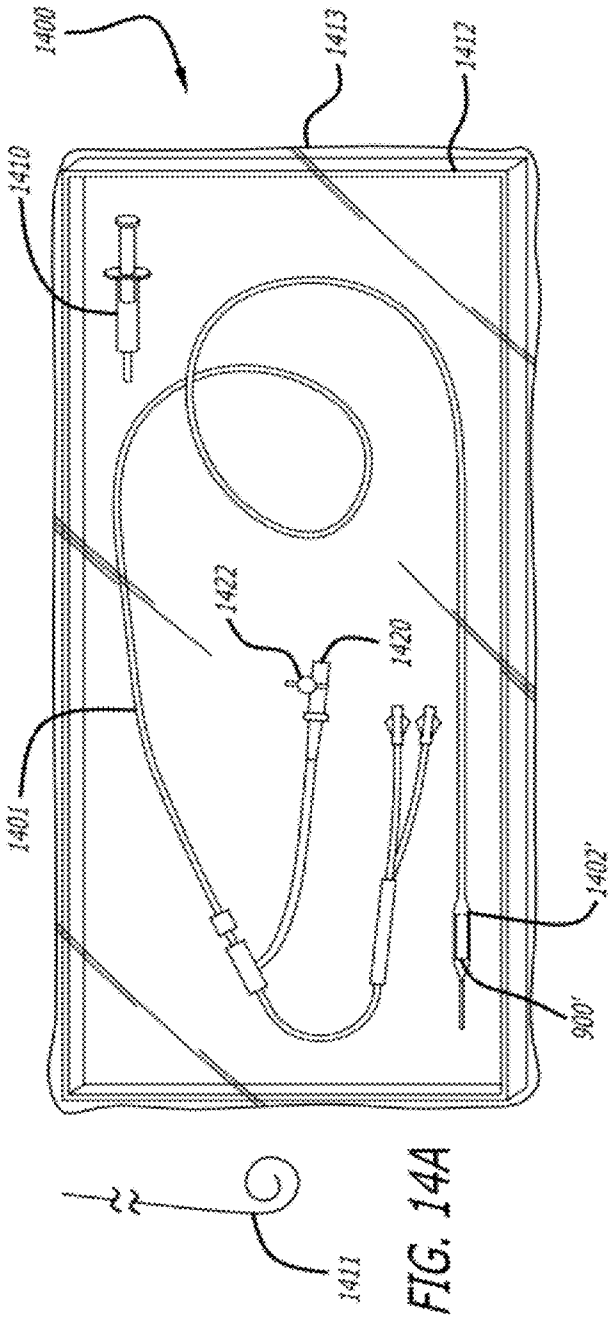


FIG. 14A

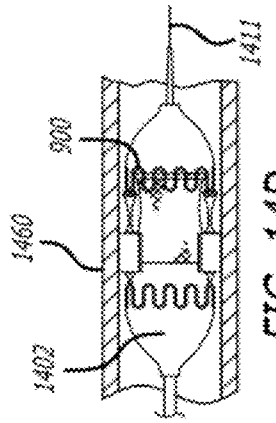


FIG. 14D

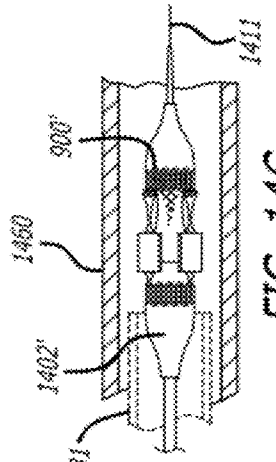


FIG. 14C

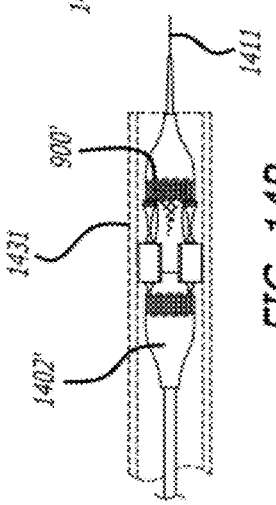


FIG. 14B

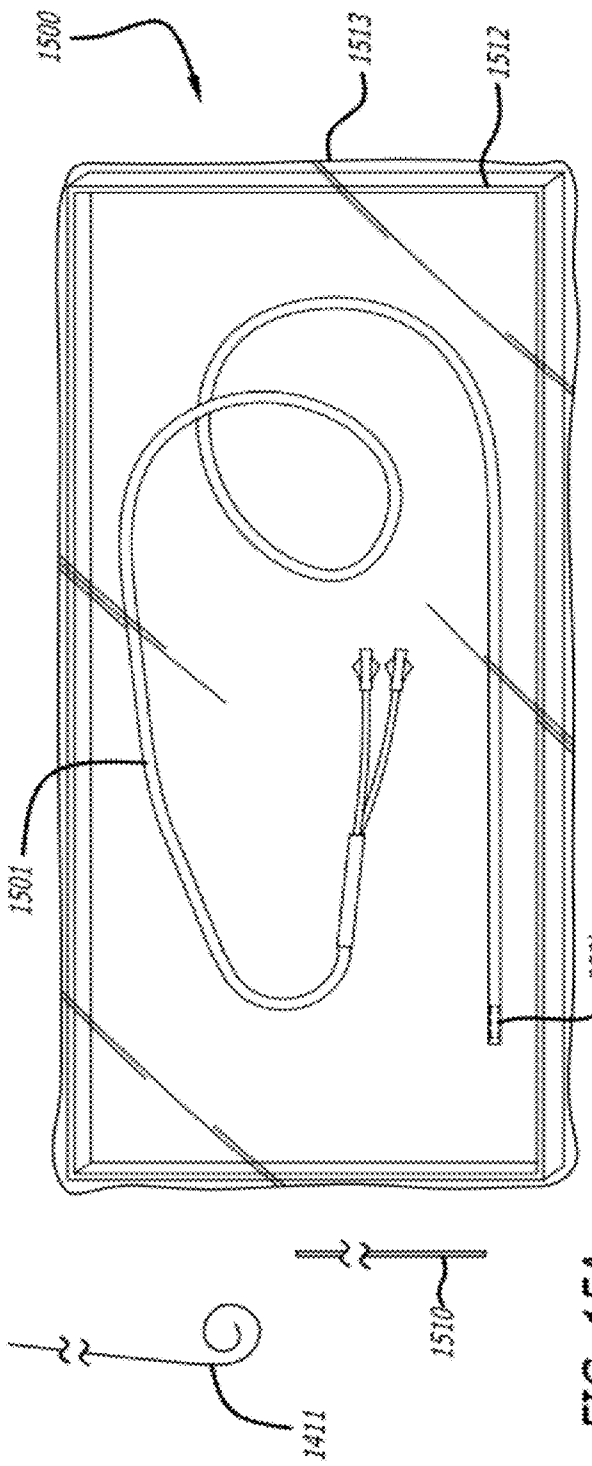


FIG. 15A

FIG. 15B

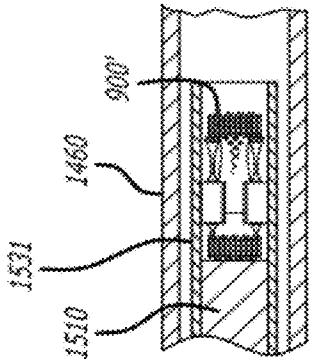


FIG. 15C

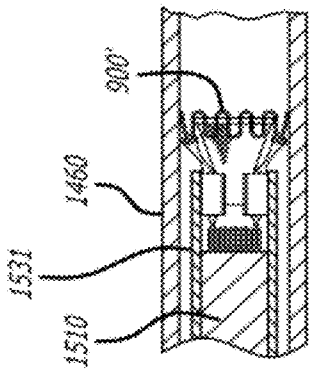


FIG. 15D

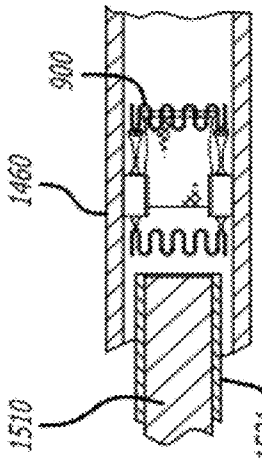


FIG. 15E

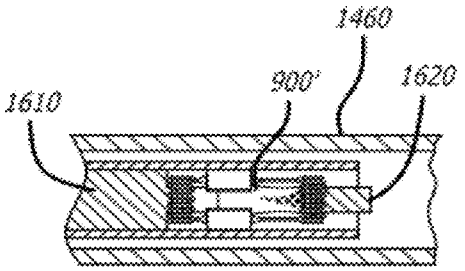


FIG. 16A

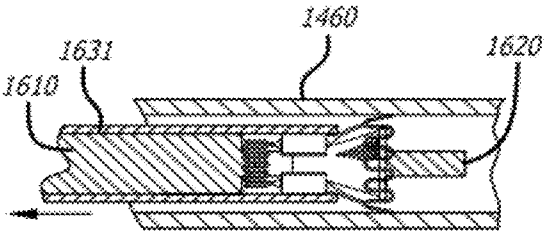


FIG. 16B

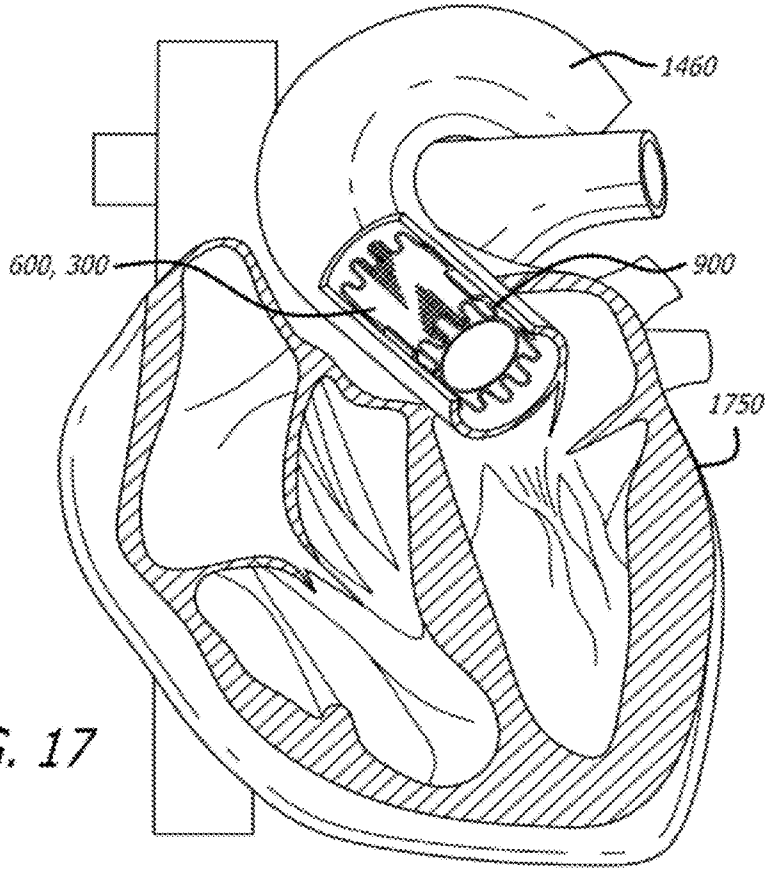


FIG. 17

PROSTHETIC VALVES FORMED WITH ISOTROPIC FILTER SCREEN LEAFLETS

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] The patent application claims the benefit of U.S. Provisional Patent Application No. 61/460,592 entitled FLEXIBLE LEAFLET AND FLEXIBLE LEAFLET VALVE filed on Jan. 5, 2011 by inventor Jeffrey Paul DuMontelle which is incorporated herein by reference.

FIELD

[0002] The embodiments of the invention relate generally to prosthetic valves.

BACKGROUND

[0003] There are four valves in the heart that serve to direct blood flow through the two sides of the heart. On the left (systemic) side of the heart are: (1) the mitral valve, located between the left atrium and the left ventricle, and (2) the aortic valve, located between the left ventricle and the aorta. These two valves direct oxygenated blood from the lungs through the left side of the heart and into the aorta for distribution to the body. On the right (pulmonary) side of the heart are: (1) the tricuspid valve, located between the right atrium and the right ventricle, and (2) the pulmonary valve, located between the right ventricle and the pulmonary artery. These two valves direct de-oxygenated blood from the body through the right side of the heart and into the pulmonary artery for distribution to the lungs, where the blood becomes re-oxygenated in order to begin the circuit anew.

[0004] All four of these heart valves are passive structures in that they do not themselves expend any energy and do not perform any active contractile function. They consist of moveable features, generally described as leaflets or cusps, that open and close in response to differential pressures on either side of the valve. The mitral and tricuspid valves are typically referred to as atrioventricular valves because they are situated between an atrium and ventricle on each side of the heart. The mitral valve has two leaflets and the tricuspid valve has three. The aortic and pulmonary valves are typically referred to as semilunar valves because of the unique appearance of their leaflets, which are shaped somewhat like a half-moon and are typically described as cusps. The aortic and pulmonary valves each have three cusps.

[0005] There are other valves in the body such as those in the peripheral vasculature. These valves are usually single leaflet structures. These valves act as gates to prevent the blood from flowing backward. For example as a leg muscle contracts, the venous vessels are compressed and the blood is pushed through a valve, as the muscle relaxes, the blood is not allowed to flow backward as the valve closes. The one-way venous valve ensures that the blood flows in one direction back towards the heart.

[0006] Human heart valve leaflets are generally formed of an endothelial layer of tissue that encloses a core of collagenous bundles. The endothelial layer has relatively few elastic fibers. The endothelium covering the surface of a leaflet typically has fine folds or corrugations that extended along this surface in a proximo-distal direction. The collagenous fibers are condensed in the center of the leaflet but loosely disposed beneath the surface endothelium. The central fibers are arranged into wavy bundles that run parallel with the base-to-apex axis of the leaflet near its atrial aspect and they are typically obliquely or irregularly disposed towards the ventricular aspect of the leaflet. The elastic fibers are typically found only in the subendothelial zone of the leaflet. The leaflet core is thicker at the peripheral basal margin of a leaflet and tapering towards its central free margin. The endothelial layers have minimal stretch but the internal collagenous structure acts as flexible structure that compensates for the differences in lengths as the valve opens and closes. This multilayer type configuration allows the leaflet to readily flex back and forth from a concave to a convex condition.

[0007] Valves may exhibit abnormal anatomy and function as a result of congenital or acquired valve disease. Congenital valve abnormalities may be well-tolerated for many years only to develop a life-threatening problem in an elderly patient, or may be so severe that emergency surgery is required in-utero or within the first few hours of life. Acquired valve disease may result from causes such as rheumatic fever, degenerative disorders of the valve tissue, bacterial or fungal infections, and trauma.

[0008] Since valves are passive structures that simply open and close in response to differential pressures on either side of the particular valve, failure modes that can develop with valves can be classified into two categories: (1) stenosis, in which a valve does not open properly, and (2) insufficiency (also called regurgitation), in which a valve does not close properly. Stenosis and insufficiency may occur at the same time in the same valve or in different valves.

[0009] Both of these abnormalities increase the workload placed on the heart as well as other organs of the body such as the liver and kidneys. In particular, the severity of this increased stress on the heart, and the heart's ability to adapt to it, determine whether the abnormal valve will have to be repaired or surgically removed and replaced. The functions of the valve may be replaced by implantation of an additional valve within the diseased valve.

[0010] Development of a prosthetic valve that can approach the overall performance of a native valve requires that such a valve be biocompatible, durable, non-thrombogenic, and exhibit advantageous hemodynamic performance.

[0011] Valve replacement surgery or valve function replacement is described and illustrated in numerous books and articles, and a number of options, including artificial mechanical valves and artificial bioprosthetic (tissue) valves, are currently available. However, the currently-available options cannot completely duplicate the advantages of native (natural) valves. Some of the available mechanical valves tend to be very durable, but are problematic in that they are thrombogenic, exhibit relatively poor hemodynamic properties and generally cause significant damage to the patient's blood cells when they are performing their function (i.e. opening and closing in the blood flow). All of these characteristics usually require lifelong anticoagulation therapy for the patient.

[0012] Some of the available bioprosthetic tissue valves may have relatively low thrombogenicity, but lack the durability of mechanical valves. This lack of durability is generally attributed to the tissue material used in the valves, where the material properties may not be well understood and therefore used improperly in the design of the valve. The material itself may be attacked by the patient's normal body defenses, resulting in calcification of the leaflets, and ultimately, failure of the valve.

[0013] Mechanical valves such as the caged ball valve, the tilting disc (single leaflet) valve, and the bileaflet valve are rigid structures; therefore it is not possible to collapse them to a diameter sufficient for safe implantation using small diameter catheters or delivery systems (e.g. smaller than twenty-nine french (29 f) or nine and seven-tenths millimeter (9.7 mm).

[0014] Other prosthetic valves, such as bioprosthetic valves manufactured using pericardial tissue, are generally flexible structures, and it is possible to collapse them to a diameter sufficient for safe implantation using small diameter catheters or delivery systems. However, bioprosthetic valves cannot be readily sterilized by common heat (autoclave) or gamma radiation sterilization processes. Bioprosthetic valves typically must be sterilized with a chemical sterilant and thoroughly rinsed to remove residual chemical sterilant prior to implantation. Chemical sterilization precludes the prosthetic valve's ability to be collapsed prior to sterilization as the tightly collapsed materials would prevent the sterilant from performing its function as the sterilant would not be able to penetrate into and between the material layers. Chemical sterilization also precludes the valve from being stored in a collapsed or compressed state because significant amounts of chemical residue would remain in folds of a compressed valve even after rinsing. Thus, currently, these prosthetic valves must be stored in a non-collapsed state, necessitating compression prior to surgery.

[0015] Tissue engineered valves have also been developed but these valves tend to lack the durability required for valve replacements and also require extensive time for construction and cell seeding, all of which make them impractical for use in normal valve replacement surgery or valve function replacement procedures as patients typically present emergently.

[0016] There is a need in the art for an improved prosthetic valve having advantageous hemodynamic performance, non-thrombogenicity, and durability with the ability to be sterilized and stored in a collapsed or non-collapsed state until implantation.

BRIEF SUMMARY

[0017] The embodiments of the invention are summarized by the claims that follow below. However, briefly, the embodiments of the invention include methods, apparatus, and systems for prosthetic valves formed with isotropic filter screen leaflets. The prosthetic valve may be applied in mammals, may use one or more flexible leaflets and may be sterilized and stored in a collapsed or non-collapsed state. An aspect of the invention is a leaflet or cusp or contiguous leaflets or cusps made from a filter screen with uniform pores having a diameter between fifteen (15) microns and sixty (60) microns that can be used to make a prosthetic valve. The filter screen material is of a biocompatible material such as polyester, polypropylene or other biocompatible material. The filter screen material may be from one-hundredth (0.01) of a millimeter to one-tenth (0.10) of a millimeter thick. The prosthetic valves may be crimped, sterilized and included in a catheter delivery system, inside a sterile barrier, ready for minimally invasive implantation without having to be rinsed prior to use.

BRIEF DESCRIPTIONS OF THE DRAWINGS

[0018] FIG. **1** is a background FIG. illustrating a woven polyester material with non-uniform openings.

[0019] FIG. **2** is a background FIG. illustrating a woven yarn material formed with strands of yarn having non-uniform openings.

[0020] FIG. **3** is a top view of woven monofilament material with uniform openings.

[0021] FIG. **4**A is a view of the woven monofilament material of FIG. **3** with a rough cut edge formed through contact method of cutting.

[0022] FIG. **4**B is a view of the woven monofilament material of FIG. **3** with a smooth sealed edge formed through a non-contact method of cutting.

[0023] FIG. **5** illustrates the woven monofilament material of FIG. **3** encapsulated with smooth endothelial tissue.

[0024] FIG. **6** is a plan view of a prosthetic valve leaflet formed out of the woven monofilament material illustrated in FIG. **3**.

[0025] FIG. **7** is an exploded view of assembly of a prosthetic valve with prosthetic valve leaflets of FIG. **6**.

[0026] FIG. **8**A is a top perspective view of a prosthetic valve with prosthetic valve leaflets of FIG. **6**.

[0027] FIG. **8**B is a bottom perspective view of the prosthetic valve of FIG. **8**A.

[0028] FIG. **9**A is a top perspective view of a prosthetic valve with three prosthetic valve leaflets in a closed condition due to back flow fluid pressure.

[0029] FIG. **9**B is a top perspective view of a prosthetic valve with three prosthetic valve leaflets in an open condition due to forward flow fluid pressure.

[0030] FIG. **10**A is a top perspective view of a prosthetic valve with two prosthetic valve leaflets in an open condition due to forward flow fluid pressure.

[0031] FIG. **10**B is a bottom perspective view of the prosthetic valve of FIG. **10**A.

[0032] FIG. **10**C is a top perspective view of the prosthetic valve of FIG. **10**A in a closed condition due to back flow fluid pressure.

[0033] FIG. **10**D is a sectional view of the prosthetic valve of FIG. **10**C in the closed condition.

[0034] FIG. **11**A is a side view of a prosthetic valve with a single prosthetic valve leaflet in a closed condition due to back flow fluid pressure.

[0035] FIG. **11**B is a side view of the prosthetic valve with a single prosthetic valve leaflet in an open condition due to forward flow fluid pressure

[0036] FIG. **12** illustrates an uncompressed prosthetic valve stored in a storage container.

[0037] FIG. **13**A illustrates an uncompressed prosthetic valve being compressed by a radial force applied by a compression device.

[0038] FIG. **13**B illustrates a compressed prosthetic valve for storage or insertion into a human being.

[0039] FIG. **13**C illustrates an exploded view of a compressed prosthetic valve being stored in a storage container.

[0040] FIG. **13**D illustrates a compressed prosthetic valve being stored in a storage container.

[0041] FIG. **14**A illustrates a delivery system for a prosthetic valve compressed onto a balloon catheter.

[0042] FIG. **14**B illustrates the balloon catheter with the compressed prosthetic valve collapsed onto a deflated balloon.

[0043] FIG. **14**C illustrates the balloon catheter with the compressed prosthetic valve collapsed onto a deflated balloon being advanced inside a vessel.

[0044] FIG. **14**D illustrates the balloon catheter with the balloon expanded to expand the compressed prosthetic valve into place as the uncompressed prosthetic valve.

[0045] FIG. **15**A illustrates a delivery system for a compressed self-expanding prosthetic valve compressed into the distal end of catheter.

[0046] FIG. **15**B illustrates the distal end of the catheter with the compressed self-expanding valve inside, being advanced along a vessel.

[0047] FIG. **15**C illustrates the distal end of the catheter with the compressed self-expanding valve being ejected into the proper position inside the vessel.

[0048] FIG. **16**A illustrates a compressed prosthetic valve with an anchor tab inside the distal end of a catheter.

[0049] FIG. **16**B illustrates a compressed prosthetic valve with an anchor tab being pulled from the distal end of a catheter.

[0050] FIG. **17** illustrates the compressed prosthetic valve inserted into and expanded in place in a heart.

DETAILED DESCRIPTION

[0051] In the following detailed description of the embodiments of the invention, numerous specific details are set forth in order to provide a thorough understanding of the present invention. However, it will be obvious to one skilled in the art that the embodiments of the invention may be practiced without these specific details. In other instances well known methods, procedures, and components have not been described in detail so as not to unnecessarily obscure aspects of the embodiments of the invention.

[0052] In accordance with one aspect of the present invention, a prosthetic valve is assembled from a plurality of the leaflets or cusps sewn together, or from the contiguous leaflets or cusps, described above, each having an inner face, an outer face, an in-flow edge, an out-flow edge and side edges. The leaflets are arranged so that at least a portion of their side edges form a substantially valve like structure having an in-flow end and an out-flow end. The adjacent leaflets are arranged so that their side edges are substantially aligned and the inner faces of the leaflets engage each other adjacent the side edges. The valve structure is movable between a closed position in which the out-flow edges of adjacent leaflets engage each other at a depth of between three millimeters and nine millimeters, and an open position in which the out-flow edges of adjacent leaflets are separated from each other except along the side edges so that the portions of the side edges of the leaflets bias the leaflets toward a partially closed position.

[0053] In accordance with a further aspect of the present invention, a method for making a prosthetic valve involves providing a section of substantially flat, flexible fifteen micron to sixty micron filter screen material, cutting a plurality of leaflets out of the flat material so that each of the leaflets has an inner face, an outer face, a proximal end, a distal end, side edges, and tab portions adjacent the distal end and extending from the side edges, aligning the side edges of adjacent leaflets together so that the inner faces of adjacent leaflets engage each other adjacent the side edges, and sewing aligned side edges together so as to form a substantially valve like structure having an in-flow end and an out-flow end.

[0054] Additionally, the plurality of leaflets can be formed using a non-contact cutting apparatus, such as but not limited to a laser, or a contact cutting apparatus, such as but not limited to a radio frequency (RF) or ultrasonic cutter.

[0055] In accordance with another aspect of the present invention, the leaflets of a prosthetic valve are comprised of fifteen micron to sixty micron filtration screen material made from biocompatible monofilament polypropylene, polyester, acetylpolymer (e.g. homopolymer (e.g. DELRIN®) or copolymer), or a natural material such as silk or spider web.

[0056] In accordance with another aspect of the present invention, a prosthetic valve manufactured from the leaflets comprised of a flexible fifteen micron to sixty micron screen material that can be sterilized utilizing gamma radiation, e-beam, ethylene oxide (EtO), heat (autoclave), or chemical sterilant (e.g. glutaraldehyde, hydrogen peroxide).

[0057] In accordance with another aspect of the present invention, a prosthetic valve manufactured from the leaflets comprised of a flexible fifteen micron to sixty micron pore size screen material that can be collapsed to a diameter less than or equal to twenty-nine french (29 f) or nine and seven-tenths millimeter (9.7 mm) and sterilized. This collapsed valve can be stored in a dry condition and can be implanted into a mammal without rinsing.

[0058] In accordance with another aspect of the present invention, a semilunar valve is assembled from three thin, flexible leaflets of fifteen micron to sixty micron filter pore size screen material, each having an inner face, an outer face, an in-flow edge, an out-flow edge, side edges and tab portions extending outwardly beyond the side edges and positioned adjacent the out-flow edge such that the leaflets are attached to each other along their side edges so as to form a substantially valve like structure having an in-flow end and an out-flow end. The tab portions of adjacent leaflets engage each other to form commissural attachment tabs and at least a portion of each commissural attachment tab is adjacent to the outer face of the adjacent leaflets.

[0059] Another aspect of the present invention is a method for manufacturing a prosthetic valve involving providing a first valve leaflet of fifteen micron to sixty micron filter pore size screen material and a second valve leaflet of fifteen micron to sixty micron filter pore size screen material, the leaflets being formed separately from each other, placing a portion of an inward face of the first valve leaflet against a corresponding portion of an inward face of the second valve leaflet so that they have a depth of coaptation at the outflow edge that is between three and nine millimeters, and attaching the inward face portions to each other. The inward face portions of the leaflets are attached at the side edges of the leaflets.

[0060] In accordance with another aspect of the present invention, a prosthetic valve includes a plurality of valve leaflets comprised of a flexible fifteen micron to sixty micron pore size screen material, each leaflet having an inner surface and an outer surface, each leaflet attached to another leaflet along an attachment line, a portion of an inner surface face of one leaflet being in facing relationship with a portion of an inner surface of another leaflet at the attachment line, and a commissural tab at an end of each attachment line. The tab having free ends configured for attachment to a blood vessel.

[0061] In accordance with another aspect of the present invention, a prosthetic valve includes a plurality of valve leaflets comprised of a flexible fifteen micron to sixty micron pore size screen material. The prosthetic valve may be pre-compressed for ready insertion. In one embodiment the prosthetic valve may be compressed or collapsed around a balloon catheter. In another embodiment the compressed prosthetic valve may be self expanding. The prosthetic valves may com-

pressed, sterilized as part of a catheter delivery system or kit, inside a sterile barrier, ready for minimally invasive implantation without having to be rinsed prior to use.

Introduction

[0062] Various authors have discussed the use of DACRON® (DuPont trademarked polyethylene terephthalate, PET, a polyester yarn (multi-filament) material similar to the material shown in background FIG. **2**) whereby the DACRON® yarn is knitted or woven into a fabric and then cut to a leaflet shape. The authors discuss the desirable tissue in-growth, however the thickness of the DACRON® as well as its limited non-uniform porosity (see typical opening in DACRON® as shown in FIG. **2**) prevents valves made from these types of leaflets from satisfactory performance. The thickness of this material, usually one millimeter (1.0 mm) to one and one-half millimeter (1.5 mm) or greater, does not allow for the leaflet to open and close properly during the normal cardiac cycle. As the patient's body defenses begin to encapsulate the cloth material, the leaflet thickness increases and the flexibility of the leaflet is further reduced.

[0063] Leaflets have been formed with multilayer woven materials such as DACRON®. The DACRON® yarn is knitted or woven into a fabric and then cut to a leaflet shape. Referring now to background FIG. **1**, a woven polyester material **100** is illustrated. Rows **101** and columns **102** of the polyester material are woven together to form the woven polyester material **100**. At the interstices of rows **101** and column **102** are a number of small, non-uniform openings **104**A-**104**C. The openings **104**A-**104**C are non-uniform in size and shape. Non-uniform openings are undesirable, as tissue is unable to grow evenly through the material **100** and strengthen it across its entire surface.

[0064] A magnified view of a square of DACRON® weave **200** is shown in FIG. **2**. Rows **201** and columns **202** of DACRON® yarn are woven at a substantially ninety degree angle to form a material with openings **204**A, **204**B, and **204**C at the interstices of the rows **201** and columns **202**. As more clearly shown in this magnified view, the openings **204**A-C are non-uniform in size and shape. Under magnification, DACRON® is seen to be a multi-filament yarn; with each row **201** and column **202** comprising smaller fibers **210**.

[0065] The thickness of woven DACRON® is usually one millimeter (1.0 mm) to one and one-half millimeter (1.5 mm) or greater. The thickness of this material does not allow for the leaflet to open and close properly during the normal cardiac cycle. As the patient's body defenses begin to encapsulate the cloth material, the leaflet thickness increases and the flexibility of the DACRON® leaflet is further reduced. The non-uniform porosity also degrades the performance of valves made from these types of materials. Non-uniform porosity promotes non-uniform encapsulation further degrading the flexibility and hemodynamic of the DACRON® leaflet over time.

[0066] While authors may have presented anisotropic, multi-layered synthetic leaflets, they have not taught that by using a single layer of isotropic material that this layer, after implantation and endothelial cell encapsulation, naturally will become one of the outer leaflet layers as the prosthetic valve integrates into the body.

Monofilament Material for Posthetic Valve Leaflets

[0067] Embodiments of the invention use a single layer isotropic synthetic material such as monofilament polyester, monofilament nylon, or monofilament polypropylene to form the valve leaflets.

[0068] Unlike prior art material, the invention uses isotropic filtration screen as a material for a valve leaflet or leaflets. Referring to FIG. **3**, one aspect of the invention uses a monofilament material **300** composed of monofilament strands **301**,**302** woven or knitted into a single layer of isotropic material. A cross section shape of the monofilament strands **301**,**302** may be round, oval, square, or rectangular, for example. The openings or pores **304**A-C at the interstices of the monofilament strands **301**,**302** have a pore size that allows fifteen (15) micron to sixty (60) micron particles to pass through them. Accordingly, a pore size between monofilaments for the material **300** may be in the range between fifteen (15) microns to sixty (60) microns, inclusively. For example, the pore size of the openings or pores **304**A-**304**C in accordance with one embodiment of the invention are approximately twenty-seven (27) microns. Usually red blood cells are about six (6) microns to eight (8) microns in diameter and approximately two microns thick, thus they are capable of passing through pores **304**A-C with a pore size of twenty-seven (27) microns relatively intact.

[0069] Unlike DACRON®, the openings **304**A-**304**C of monofilament material **300** are generally of uniform size. With uniform openings, tissue in-growth or endothelialization occurs uniformly throughout and provide a strengthening layer over the entire surface. Additionally, the smaller thickness or cross-section distance of the monofilament fiber **301**, **302** which forms the uniform openings **304**A-**304**C allow the material **300** to flex readily between a concave surface and a convex surface with little to no damage to the material **300**.

[0070] The thinner single layer of monofilament material **300** also promotes faster endothelialization. At about one-tenth the thickness of DACRON®' the monofilament material **300** is less likely to induce calcification as the amount of material will be substantially encapsulated by native tissue. Endothelization may also promote better hemodynamics and reduce thrombogenicity and rejection of the prosthetic valve.

[0071] Monofilament material **300** is also more resilient than some of the prior art materials. For example, after opening and closing approximately forty million times, solid sheet materials such as MYLAR® may develop a crease from plastic deformation of the material, eventually leading to valve failure. The smaller monofilament strands making up monofilament material **300** have a smaller critical radius thus they are more resistant to the effects of plastic deformation. The small cross section distance of the monofilament strands **301**, **302** which forms the uniform openings **304**A-**304**C allow the monofilament material **300** to flex readily between a concave surface and a convex surface with little to no damage to the monofilament material **300**.

[0072] Unlike natural or cross-linked (e.g. glutaraldehyde fixed) tissue, the monofilament material **300** may be readily sterilized by heat and gamma radiation. Bioprosthetic tissue is generally limited to chemical sterilization such as by two to four percent glutaraldehyde. Thus, the monofilament material **300** is the preferred choice of material for a prosthetic valve leaflet.

[0073] The monofilament strands **301**,**302** are made from biocompatible polypropylene, polyester, silk, spider web, or other biocompatible material. The thickness of the woven or knit material is between one hundredth of a millimeter (0.01 mm) and one-tenth of a millimeter (0.10 mm). According, the cross section distance of a monofilament strand may be in the range of one hundredth of a millimeter (0.01 mm) and one-

tenth of a millimeter (0.10 mm), inclusively. The screen material fabricated from the monofilament strands **301**,**302** may be cut into leaflets.

[0074] A leaflet may be cut from the filter screen material using a non-contact method such as a laser to ensure that the cut edges of the leaflet do not substantially have any extending fibers. The leaflet could also be cut from the material using a heat contact method, such as with a radio frequency (RF) or ultrasonic cutter, as long as the edges of the finished leaflet do not substantially have any extending fibers. Using the non-contact or heat contact methods described ensures that the edges of the leaflet are fused and prevents the leaflet from coming apart or the monofilaments from unraveling. The leaflet will be less thrombogenic as there will be no fibers extending out from the edge of the leaflet that would prompt a thrombogenic response from the body.

[0075] Referring now to FIG. **4**A, an edge **410** is illustrated in the monofilament material **300** formed by a shearing method of cutting. As a shearing method of cutting was used, the edge in the monofilament material **300** is a rough-cut edge **410**. A rough-cut edge **410** edge may be satisfactory when the monofilament material **300** is coupled to another surface. A suture, for example, may deter the woven monofilament material from unraveling in the leaflet at the rough cut edge **410**. The rough cut edge **410** may also be heated until the rows and columns at the edge melts. Melting the edge may fuse or seal the rows and columns of monofilament strands together to keep them from unraveling. Typically, at least one edge of the leaflet is an open edge (e.g. outflow edge) that is preferably sealed to avoid unraveling.

[0076] Referring now to FIG. **4**B, a noncontact cutting or cutting method may be used to cut an edge in the monofilament material **300**. A laser is an example of a noncontact method of cutting the material, while an ultrasonic, radio frequency (RF) cutter or heated blade or die may be an example of a contact cutting method. Both cutting methods leave a smooth sealed or fused edge **412** in the monofilament material **300**. The prosthetic valve leaflet may have one or more of its edges cut in this manner so that one or more respective edges are a smooth sealed edge **412**.

[0077] The monofilament material, after being cut into a valve leaflet, may be coated with a collagen material that surrounds and penetrates into the monofilament screen to form a mechanical lock. The monofilament material acts as a scaffold for cell growth in-vivo allowing mammalian autologous cells to adhere to, and to grow on, the scaffold. This growth occurs naturally after implantation in the mammal thereby creating a smooth, highly biocompatible, non-thrombogenic surface.

[0078] Referring now to FIG. **5**, a top view of tissue **510** grown into the monofilament material **300** is illustrated. To seal the openings **304**A-**304**C within the monofilament material **300**, tissue **510** is allowed to grow into and around the columns and rows of the monofilaments. In FIG. **5**, the smooth endothelial tissue **510** substantially encapsulates the monofilament material **300**. After twelve to forty-eight hours of exposure to in-vivo blood flow, the smooth endothelial tissue **510** can substantially encapsulate the monofilament material **300**. In one embodiment, for example, a twenty-seven micron monofilament material was substantially encapsulated by smooth endothelial tissue **510** after less than twelve hours.

Prosthetic Valve Leaflets

[0079] A leaflet made from the material **300** described above presents to the blood flow a surface that is initially porous and will allow blood components such as red blood cells to pass through it. While a red blood cell will pass through the screen material, the screen still presents a restriction to flow much like a window screen partially blocks air flow through a window. When these leaflets are used to form a prosthetic valve, this type of screen material in the blood flow will initially prevent lysis, or destruction, of the red blood cells when the leaflet sections close, but still provide enough resistance to the blood flow to act as a one-way valve.

[0080] As the body reacts to the material **300**, endothelial cells will form on the surface of the screen and gradually grow on and anchor themselves through the screen material. This endothelialization will gradually reduce the screen porosity with the patient's own native cells and the porosity of the screen will naturally decrease and the valve will become more competent and less regurgitant. Over time, it is expected that the encapsulated leaflet will begin to take the shape of a natural leaflet and the layer of screen material will take the role of an outer, less elastic layer of the leaflet while the patient's own tissue will develop into the other layers such as the inner more elastic layer.

[0081] Endothelization may also improve the hemodynamics and reduce the thrombogenicity of the prosthetic valve. The smooth endothelial tissue reduces fluid resistances through the valve. Also, because the endothelial layer is formed of the patient's own native cells, there is less likelihood of implant rejection.

[0082] Referring now to FIG. **6**, an example of a prosthetic valve leaflet **600** formed out of the woven monofilament material **300** is illustrated. The monofilament material **300** is cut into the shape of the prosthetic valve leaflet **600**. One or more of the edges of the valve leaflet are cut using the non-contact cutting or heat cutting method to provide a smooth, sealed edge. The leaflet can also be referred to herein as a cusp.

[0083] The exemplary prosthetic valve leaflet **600** has an inner surface **602**A and an outer surface **602**B. The leaflet **600** further has an inflow end **606**B and an outflow end **606**A. Near the inflow end **606**B, an inflow edge **608**B is cut into the material **300**. Near the outflow end **606**A, an outflow edge **608**A is cut into the material **300**. A left-side edge **610**L and a right-side edge **610**R, forming a pair of side edges **610**, are cut into the material **300** to further form the valve leaflet **600**. A left-tab portion **604**L and a right-tab portion **604**R are also cut into the material **300** to form a pair of tab portions **604** in the leaflet **600**.

[0084] One or more of the prosthetic valve leaflets **600** may be used to form a prosthetic valve to be inserted within a mammalian body. The prosthetic valve functions as a passive one-way check valve. In the case of three leaflet valves, an adjacent left tab and right tab of adjacent leaflets are coupled together to form a joint tab. Fluid flow in the opposite direction of the prosthetic valve may cause the outflow edges **608**A of prosthetic valve leaflets **600** to push together and engage, thereby blocking the regurgitant flow. Similarly, two valve leaflets may have their tabs coupled together to form a check valve where regurgitant flow may also cause the outflow edges **608**A to push together and engage to close the valve. In another embodiment with a single valve leaflet **600**, the tab **604**A or **604**R and inflow edge **608**B may be sewn to a vessel sidewall while the outflow edge **608**A flaps open and closed against an opposite vessel sidewall.

[0085] While FIG. **6** illustrates one shape of a prosthetic valve leaflet **600** that may be cut from the isotropic screen

material, other shapes for a valve leaflet may cut as well and used in a prosthetic valve. For example, other shapes of valve leaflets are disclosed in U.S. Pat. No. 2,822,819 issued to Geeraert; U.S. Pat. No. 3,197,788 issued to Segger; U.S. Pat. No. 4,297,749 issued to Davis; U.S. Pat. No. 4,388,735 issued to Ionescu; U.S. Pat. No. 4,470,157 issued to Love; U.S. Pat. No. 4,501,030 issued to Lane; U.S. Pat. No. 6,338,740 issued to Carpentier; U.S. Pat. No. 6,454,799 issued to Schreck; U.S. Pat. No. 6,893,460 issued to Spenser; and U.S. Pat. No. 7,044,966 issued to Svandize et al; as well as US Pat. App. Pub. Nos. 2004/0225356 by Frater, 2006/0235511 by Osborne, 2007/0270944 by Bergheim et al, and 2010/0174361 by Bailey et al.; all of which are incorporated herein by reference.

Prosthetic Values for Mammals

[0086] Referring now to FIG. **7**, an exploded view of the assembly of a prosthetic valve utilizing three leaflets **600** is illustrated. The three leaflets **600**A-**600**C are coupled together to form a tri-leaflet structure **702**. The adjacent tabs of each leaflet **600**A-**600**C are coupled together to form joint tab **804**. A left edge **610**L is coupled to a right edge **610**R of an adjacent leaflet (refer back to FIG. **6**). A sewing ring **703** formed of the monofilament material **300** may be formed and coupled to the tri-leaflet **702** along each outflow edge **608**B. Although depicted as a separate piece, sewing ring **703** may be unitarily formed from the inflow edges of the tri-leaflet structure **702**, e.g. by rolling the edges. Sewing ring **703** may be used to anchor the inflow edge of the prosthetic valve, for example by coupling the sewing ring **703** to the inner wall of an outer frame or stent or directly to an artery.

[0087] With the tri-leaflet structure **702** and the sewing ring **703** coupled together, a first embodiment of a prosthetic valve **750** is formed. The prosthetic valve **750** may be sewn directly to an artery or other tissue or may be further coupled to a frame **704**, for example. The valve **750** may have joint tabs **804** inserted into tab openings **904** within the frame **704**. The valve **750** is inserted into the inner hollow area of the frame **704**, to form another embodiment of a prosthetic valve **900**.

[0088] Frame **704** may be constructed of a variety of metals and polymers so long as the material is flexible, supportive, capable of being collapsed and subsequently expanded (if applicable), and biocompatible. Stainless steel, gold, titanium, cobalt-chromium alloy, tantalum alloy, Nitinol (Nickel Titanium Naval Ordinance Laboratory) are examples of metals used in stent frames. Nitinol is an ideal metal because it is highly biocompatible, corrosion resistant, very flexible and has excellent shape memory when heated to a certain temperature. Shape memory allows a Nitinol stent to be cooled, compressed, and retained in a compressed state, and surgically inserted. As the Nitinol warms, it will return to its uncompressed state without deformation.

[0089] Certain polymers such as acetylpolymer, polypropylene, silicone, polyethylene and polyurethane have also found use as stent materials. The number and type of polymers developed for use in medical devices is expanding as different polymer types, chemistries and manufacturing processes are used to produce devices or device coatings with a wide variety of functional characteristics. Shape-memory polymers can also be used to produce a device that will transition from a temporary state to a different (permanent) state through the inducement of a stimulus of heat or cold.

[0090] The valve **750**, **900** is compressible by an optional compression step **706**. The valves **750**, **900** can be stored in a container for later insertion into a body. The valves **750**, **900** after assembly can be compressed by the optional compression **706** and inserted into a body **750**. Alternatively, the valves **750**, **900** may be stored in containers **708**, **708'**. The container includes a base **708**B with one closed end and one open end, and a cap **708**A to close over the open end. If the valves **750**, **900** are compressed by the optional compression step, the storage container **708'** may be used as it is smaller and more compact than the storage container **708**. The storage container **708** is sized to store the non-compressed valve.

[0091] In one embodiment of the invention, the prosthetic valve **900** is compressed and included in a delivery system or kit, such as a catheter delivery system. Alternatively, the prosthetic valve **900** is compressed and coupled to the catheter and included as part of the delivery system. In either case, the collapsed valve is sterilized and stored in the collapsed state.

[0092] Pre-compression and delivery in a sterilized state **708**,**708'** may be advantageous as a timesaving measure and safety measure. A valve delivered in a sterile compressed state is ready for insertion without the surgeon needing to manually compress, and possibly damage or contaminate the valve. Prosthetic valve **750**,**900** may be compressed and subsequently sterilized during the manufacturing process using gamma radiation, e-beam, ethylene oxide (EtO), heat, or chemical sterilization. Bioprosthetic tissue valves cannot be readily sterilized with heat or gamma radiation without damaging the cross-linked tissue of the valves. Bioprosthetic valves may be delivered in a chemical sterilant, however bioprosthetic valves cannot be safely sterilized and stored pre-compressed. The chemical sterilant cannot readily penetrate into and between the layers of the compressed bioprosthetic valve and the chemical sterilant must be rinsed off before valve insertion, and a bioprosthetic valve in a compressed state has recesses or folds in the leaflets that would prevent adequate rinsing. Therefore, an advantage of using material **300** to form the leaflets is delivery of a pre-compressed sterile valve ready for surgical insertion.

[0093] Referring now to FIGS. **8**A-**8**B, further details of the tri-leaflet prosthetic valve **750** are now described. FIG. **8**A illustrates a top view of the tri-leaflet prosthetic valve **750**, while FIG. **8**B illustrates a bottom view of the tri-leaflet prosthetic valve **750**. The prosthetic valve operates like a check valve. The tri-leaflet prosthetic valve **750** is opened when open flow pressure **801** is experienced in one direction. The tri-leaflet prosthetic valve **750** is closed when a closed flow pressure **802** is experienced in the opposite direction. During an open flow pressure **801**, the outflow edges **808**A-**808**C of each of the respective leaflets **600**A-**600**C are pushed away from each other so that the valve remains open. In the case of closed flow pressure, the edges **808**A-**808**C and upper part of the face of each leaflet **600**A-**600**C respectively, close against each other engaging to seal during a backflow of fluid, generating the closed flow pressure **802**.

[0094] Left-tab portion **604**L of one leaflet and a right-tab portion **604**R of an adjacent leaflet are coupled together to form a joint tab **804**A-**804**C, collectively referred to as joint tabs **804**. Similarly, left side edge **610**L of one leaflet is coupled to the right side edge **610**R of an adjacent leaflet to form side edges **810**A-**810**C of the valve **750**. Together, the joint tabs **804** and the side edges **810** form commissure portion **830**A-**830**C as illustrated in FIG. **8**A. Collectively, the three commissure portions **830**A-**830**C may be referred to herein as commissure portions **830**. Although this embodiment is depicted comprising joint tabs **804**, it should be

known that joint tabs are optional to the functionality of prosthetic valves. Thus, the commissure portions **830** may comprise only side edges **810** without deviating from the scope of the invention. The inflow edge **608**A of each leaflet **600**A-**600**C is coupled to the sewing ring **703** such as shown by the edge **803**C in FIG. **8**A. FIG. **8**B better illustrates the inflow edge of each leaflet **600**A-**600**C coupled over the sewing ring **703**.

[0095] As mentioned previously, the valve **750** may be directly sewn into an artery or other flow vessel within a mammalian body. However, to provide further support structure for the valve **750**, a frame or stent may be provided as previously discussed.

[0096] Referring now to FIGS. **9**A-**9**B, the valve **750** is illustrated coupled to the stent/frame **704** to form the valve **900**. The valve **750** is inserted inside the hollow structure of frame **704**. Joint tabs **804**A-**804**C of the valve **750** may be inserted into tab openings **904**A of the frame **704**. The valve **900** is in a generally closed position **900**A as shown in FIG. **9**A. The valve **900** is in a generally open condition **900**B as shown in FIG. **9**B.

[0097] The frame/stent **704** includes compressible S-shaped rings **902**A-**902**B coupled together by two or more struts **901**A-**901**C. Each strut **901**A-**901**C includes a tab opening **904** for attachment of the joint tab **804**A-**804**C of the tri-leaflet valve **750**. The compressible S-shaped rings **902**A-**902**B can be compressed so that the circumference and diameter of the valve **900** may be reduced. Once compressed the valve can be stored in a more compact state and ready for insertion into a body. If the frame/stent is constructed of a shape memory metal or polymer, the compressed state can be maintained by cooling the valve **900** after compression or by using some form of mechanical restraint.

[0098] FIG. **9**A illustrates valve **900** experiencing a closed flow pressure such that each of the valve leaflets **600**A-**600**C have been pushed together to engage at the outflow edge. The resulting coaptation at the outflow edge, seals the valve so that minimal fluid can leak through the closed valve **900**A.

[0099] FIG. **9**B illustrates an open flow pressure pushing through the inflow end of the valve **900**. The inflow pressure passing though the internal portion of the valve flexes each leaflet **600**A-**600**C so that the outflow edge of each is pushed open. Fluid is allowed to pass freely through the opened valve **900**B.

[0100] As mentioned herein, one or more valve leaflets **600** with the monofilament material **300** may be used to form a prosthetic valve. FIGS. **7**, and **8**A-**8**B, and **9**A-**9**B, illustrate three valve leaflets **600**A-**600**C being used to form a prosthetic valve **750**,**900** with the monofilament material **300**. However, two valve leaflets **600** may also be used to form a prosthetic valve with the monofilament material **300**.

[0101] A two leaflet valve may be manufactured by forming a first and second valve leaflet of 15 to 60 micron filter screen material. The two leaflets are placed together with a portion of an inward face of the first valve leaflet against a corresponding portion of an inward face of the second valve leaflet so that they have a depth of coaptation that is between three and nine millimeters. The inward face portions are then attached to each other side edges of the leaflets by sewing or other form of adhesion. Exemplary embodiments of two leaflet valves are illustrated in FIGS. **10**A-**10**D.

[0102] Referring now to FIGS. **10**A-**10**B, a pair of valve leaflets **600**A-**600**B formed of monofilament material **300** are illustrated coupled together to form a prosthetic valve **1000**. The prosthetic valve **1000** includes the valve leaflets **600**A-**600**B coupled together to form joint tabs **804**A-**804**B, a left-side edge **810**A, and a right-side edge **810**B. The prosthetic valve **1000** further includes a sewing ring **703** coupled to each of the valve leaflets **600**A-**600**B.

[0103] A top view and a bottom view of the prosthetic valve **1000** are respectively shown. FIGS. **10**A-**10**B illustrate the prosthetic valve **1000** in an open condition. FIGS. **10**C-**10**D illustrate the prosthetic valve **1000** in a closed condition.

[0104] In FIG.**10**A the sewing ring and inflow edges are depicted at the bottom of the illustration. The open flow pressure flows from the bottom into the sewing ring **703**, through valve body, and out the top of the valve at the outflow end. The open flow pressure pushes the outflow edges apart allowing fluid to freely pass through the valve **1000**.

[0105] In FIG. **10**B the sewing ring and inflow edges are depicted at the top of the illustration. The open flow pressure flows through the sewing ring, valve body, and outflow end in the same manner as FIG. **10**A although from an opposite perspective.

[0106] In FIG. **10**C, the closed flow pressure at the top of the illustration pushes prosthetic valve **1000** into a closed valve condition. The closed flow pressure pushes back against the outflow edges of each valve leaflet **600**A-**600**B. The closed flow pressure against the outflow edges forces the valve leaflets **600**A-**600**B to flex towards each other and form a concave surface such that the surface of each further couple together to close the valve and shut off fluid flow. A clearer depiction of the closed state of an exemplary valve **1000** is illustrated in the side view of FIG. **10**D.

[0107] Referring now to FIG. **10**D, the valve leaflets **600**A and **600**B are experiencing a closed flow pressure which has pressed them together such that their outflow edges have engaged. The closed flow pressure pushes on the concave portion of the valve leaflets **600**A-**600**B, causing the outflow edges to first touch and then coapt. The monofilament material **300** is flexible so that not only the edges merge together but further portions of the valve leaflet merge together, such that a coaptation depth **1050** is formed. Not only is the material **300** flexible, it is also strong and can withstand cycles of flexing between a concave and a convex surface without breaking.

[0108] The contact between edges where the leaflets are in opposition to each other is usually referred to as the coaptive edge, coaptive depth, edge of coaptation, depth of coaptation or simply coaptation. The valve comprised of the filter screen leaflets will be constructed in such a manner so that the coaptive depth is between three millimeters to nine millimeters but ideally about six millimeters to eight millimeters. A coaptive depth allows the edges of each leaflet to properly support the other leaflet. A larger coaptive depth distributes the closing force over a greater contact surface and reduces damage to the outflow edges of the leaflets. After the endothelization of the leaflets, this depth of coaptation prevents the delicate layers of cells from being damaged as the edges of the leaflets essentially experience lower tensile forces and the closing forces are carried over a larger surface area. The bulk of the force is handled by the leaflet surface structure at the point of coaptation.

[0109] Referring now to FIG. **11**A and **11**B, a valve **1100** is depicted within a vessel such as a vein **1102** or other type of cylindrical-like (cylindrical or semi-cylindrical) shaped vessel. The valve **1100** comprises a single valve leaflet **600**. The

leaflet **600** has an edge coupled to the inner wall **1104** of the vessel **1102** by a suture **1101**, for example.

[0110] FIG. **11**A illustrates the valve **1100** in a closed position due to closed flow pressure. The valve leaflet **600** extends out and presses up against the wall **1104** of the vessel **1102**. The valve leaflet is longer than the diameter of the vessel **1102** and forms a coaptive depth **1150** with the vessel wall **1104**. As with the coaptive depth along the edges of opposing leaflets, the coaptive depth **1150** distributes the closing force over a greater contact surface and reduces damage to the outflow edge of the leaflet **600**.

[0111] FIG. **11**B illustrates the valve **1100** in an open position due to open flow pressure. The leaflet **600** has flexed into a position **600'**, as illustrated in FIG. **11**B, to allow fluid flow past the valve **1100**.

[0112] Referring now to FIG. **12**, the valve **900** may be stored in a storage container **708** in an uncompressed condition ready for surgical insertion. Alternatively, the valve **900** can be compressed into a compressed valve **900'** and stored in a compression storage container **708'**, such as illustrated in FIG. **13**C. The valves **900**,**900'** in the storage containers **708**, **708'** may be included as part of a delivery system kit. Alternatively, the valve **900** can be compressed and removably coupled to a catheter as part of a delivery system kit (e.g., see FIGS. **14**A-**14**D,**15**A-**15**D, and **16**A-**16**B and the description thereof). An uncompressed valve **900** may be compressed to a compressed valve **900'** prior to surgery. To compress the valve **900**, a force **1300** is typically radially applied to the valve **900** to compress it to the compressed valve state **900'**, such as shown in FIGS. **13**A-**13**B.

[0113] The diameter of the storage container **708'** is significantly smaller than the diameter of the storage container **708**. The compressed valve **900'** has its compressible S-shaped rings **902**A-**902**B compressed into a compressed state as illustrated by the compressed rings **902**A'-**902**B' in FIG. **13**C. The valve **750** is also compressed along with the stent/frame to a compressed state **750'**.

[0114] Compression storage container **708'** may have a diameter sufficiently narrow to physically keep the compressed valve **900'** in a compressed state during ambient temperature shipment and storage. Prior to surgical insertion, if the stent is constructed of a shape memory material, the compressed valve **900'** may be subjected to cool temperatures to retain the compressed state once removed from the compression storage container **708'** prior to loading into a delivery system. It may be advantageous to keep the valve **900** in a compressed state so that the surgeon does not have to recompress the valve **900** prior to surgical insertion.

Catheter Delivery Systems and Kits

[0115] Minimally invasive medical procedures are aimed at reducing the amount of extraneous tissue damage during diagnostic or surgical procedures, thereby reducing patient recovery time, discomfort, and deleterious side effects. The average length of a hospital stay for a standard surgery may also be shortened significantly using minimally invasive surgical techniques. Patient recovery times, patient discomfort, surgical side effects, and time away from work may be reduced with minimally invasive surgery.

[0116] One type of minimally invasive medical procedure uses a catheter to deliver a prosthetic valve to a site within a body channel. For example, in percutaneous aortic valve replacement or Transcatheter Aortic Valve Implantation (TAVI), a replacement valve compressed on a balloon catheter is passed through a hole in the groin via a puncture of the femoral artery and advanced up to the ascending aorta of the patient. The replacement valve is positioned directly inside the diseased aortic valve and the balloon is inflated to secure the valve in place. The transfemoral approach may be performed with general anesthesia and may be preferable for patients who are not candidates for open chest surgery due to age or infirmity.

[0117] A balloon catheter may be used with a compressed valve mounted on the balloon. A tubular catheter may be used that constrains a compressed self expanding valve to deliver the valve to a desired location. Example delivery systems include U.S. Pat. No. 5,840,081 issued to Andersen et al.; U.S. Pat. No. 6,682,558 issued to Tu et al.; U.S. Pat. No. 6,893,460 issued to Spenser et al.; and U.S. Pat. No. 8,016,877 issued to Seguin et al. as well as US Pat. App. Pub. Nos. 2004/0225354 by Allen et al.; 2007/0239269 by Dolan et al.; 2007/0027534 filed by Bergheim et al.; 2009/0192585 by Bloom et al., 2009/0192586 by Tabor et al.; 2010/0217371 by Noone et al.; 2010/0217385 by Thompson et al.; 2010/0234940 by Dolan; 2011/0202128 by Duffy; 2011/0251679 by Wiemeyer et al.; 2011/0257733 by Dwork; 2011/0264198 by Murray III et al.; and 2011/0264203 by Dwork et al.; all of which are incorporated herein by reference.

[0118] Referring now to FIG. **14**A-**14**D, a compressed prosthetic valve **900'** may be included as part of a delivery system or kit **1400**. In one embodiment, the kit **1400** may include a catheter **1401** with a valve **900'**, an inflation syringe **1410**, a tray **1412**, a guide wire **1411**, and a container **1413**. A collapsed or compressed valve **900'** is located at the distal end of the catheter **1401**, ready for insertion and deployment. Unlike prior art systems, the compressed prosthetic valve **900'** is ready to be implanted without having to be rinsed, compressed, sterilized, or placed on a catheter.

[0119] The container **1413**, may be a bag, box, case, tray with a lid or other sealed package to contain the catheter **1401** and valve **900'**, the inflation syringe **1410**, and optionally the guide wire **1411** and the tray **1412**. The sealed container **1413** provides a sterile barrier to maintain the contents in a sterile state until they are to be used in surgery. The sterile barrier isolates the sterile devices inside from the non-sterile world outside. The container **1413** may be a solid plastic bag, Tyvek or paper bag or combination of solid plastic and Tyvek or paper bag. It may also be a tray with a Tyvek or paper "lid" sealed to it or a tray with a lid taped to or otherwise adhered to the tray. The tray may be wrapped with a paper wrap (e.g. sash wrap) that is placed around the tray. Sash wrap is commonly used to wrap a stainless steel tray with a lid before autoclaving and prevents the tray and lid from opening during sterilization and transport. The outer wrap creates a "torturous path" that prevents organisms from penetrating into the sterile area.

[0120] Guide wire **1411** is generally inserted first and guided to the area of the diseased or faulty valve. The catheter **1401** is advanced along the guide wire **1411** until the compressed valve **900'** is at the diseased valve. In some procedures, the compressed valve **900'** may be inserted directly inside the diseased valve.

[0121] In one embodiment of the invention, the compressed valve **900'** is removably collapsed around a deflated balloon **1402'** as shown in FIG. **14**B. The balloon **1402'** is temporarily located within both the open leaflets and the frame/stent. A pump or syringe **1410** of the catheter **1400** may then be used to pump a fluid such as saline down the catheter shaft to

expand the deflated balloon **1402'** into its expanded state of the balloon **1402**. The catheter **1401** may include an optional removable sheath **1431** that may be slid over the deflated balloon **1402'** and the compressed valve **900'** for insertion. For delivery, the optional sheath **1431** is retracted such as illustrated in FIG. **14**C.

[0122] In FIG. **14**C, the distal end of the catheter with the compressed valve **900'** collapsed around the deflated balloon **1402'** is advanced inside a vessel **1460**. When the compressed valve **900'** reaches the desired location inside the vessel **1460**, the deflated balloon **1402'** is inflated to expand the compressed valve **900'** into the non-compressed or expanded valve **900**.

[0123] FIG. **14**D illustrates the inflated balloon **1402** with expanded valve **900** inside vessel **1460**. Deflated balloon **1402'** may be inflated using inflation syringe **1410** filled with a saline solution. The inflation syringe **1410** is coupled to an inlet **1420** and used to inject saline solution through the stopcock **1422**. The saline solution travels through catheter **1401** and inflates the deflated balloon **1402'** thereby expanding valve **900'** to expanded valve **900**. The expanded valve **900** may be expanded to a diameter slightly greater than the diameter of the vessel **1460** such that the sides of the valve **900** anchor to the sidewalls of vessel **1460**. Stopcock **1422** may be closed to maintain pressure in the inflated balloon **1402**. Once the valve **900** is deployed, stopcock **1422** is opened to relieve the fluid pressure inside the catheter and deflate the balloon **1402**. The catheter **1401** and balloon **1402'** are then removed leaving the valve **900** behind.

[0124] A catheter delivery system may also be used to deliver a compressed self-expanding valve. In one embodiment, the compressed self-expanding valve would be placed within restrictive structure of the delivery system, to prevent the expansion of the valve, prior to placement within a body. The frame or stent of the compressed valve may be constructed of a shape memory metal or polymer such as Nitinol. The valve would be pushed out of the restrictive structure or the restrictive structure could be pulled away from the valve and the valve allowed to self-expand to its original shape within the vessel.

[0125] Referring now to FIG. **15**A, a catheter delivery kit and system **1500** for a self-expanding prosthetic valve is shown. System **1500** comprises catheter **1501** with a compressed valve **900"** removably coupled thereto inside a hermetically sealed sterile container **1513**. The container **1513** provides a sterile barrier to maintain the contents, including the catheter **1501** and the valve **900'**, in a sterile condition during shipping and storage, until ready for surgery. A pushrod **1510** and guide wire **1411** may be included as part of the kit **1500** and optionally contained within the container **1513**. The compressed self-expanding valve **900'** is located at the distal end of the catheter, ready for insertion and deployment.

[0126] In FIG. **15**B, the compressed self-expanding valve **900'** is shown inside catheter **1501**. The tube **1531** of the distal tip of catheter **1501** acts as a restrictive structure to mechanically restrain the shape memory stent of the compressed self-expanding valve **900'** from self-expanding prior to proper position in the body. The tubular catheter **1501** is advanced inside vessel **1460** until the valve **900'** is in a proper position to be deployed. Pushrod **1510** may act as a stop to prevent the valve **900'** from sliding backwards into the tube **1531** of the catheter **1501** during advancement of the catheter.

[0127] In FIG. **15**C, the compressed self-expanding valve **900'** has reached a proper deployment position and a pushrod **1510** inserted into the tube **1531** is shown ejecting the valve **900'** out of an open end from the restrictive tubular structure **1531** of catheter **1501**. Once free of the confining tip of catheter **1501**, the valve **900'** expands to its uncompressed state, securing the valve to the sidewalls of the vessel **1460**. A shape memory stent that is a self expanding stent may be preferred for use in a self-expanding valve. A shape memory stent will warm up from the body heat of the patient and return to its uncompressed state with little to no deformation. Once the compressed valve **900'** has been deployed as the uncompressed valve **900** and secured to the vessel **1460**, the catheter may be withdrawn. The size (e.g., diameter) of the uncompressed valve and stent is selected to match the vessel or artery in which it is to be deployed. Uncompressed prosthetic valves are typically provided in diameters from ten millimeters (10 mm) to thirty-five millimeters (35 mm), inclusive, in either odd or even size designations.

[0128] Referring now to FIG. **16**A-**16**B, in an alternate embodiment of the delivery kit **1500** for the compressed self expanding prosthetic valve **900'**, an anchor tab **1620** extends from a rod **1610** out of the catheter. The anchor tab **1620** may be a hook, gripper, clip, or an inflatable balloon. The anchor tab **1620** may be used to anchor to the sidewall of the vessel **1460** to aid in ejecting the compressed self expanding prosthetic valve **900'** from the tube **1631** near the tip of catheter. Instead of using a pushrod **1510** to fully eject the compressed valve **900'**, the anchor tab **1620** may be secured to the vessel **1460** and the compressed valve **900'** may be pulled out of the restrictive structure by withdrawing the tube **1631** of the catheter. It may be advantageous to pull instead of push the compressed valve **900'** out of the catheter to reduce deformation of the stent and damage to the valve **900**. Once the valve **900** is deployed, the anchor tab **1620** may be released and fully withdrawn with the catheter.

[0129] Referring now to FIG. **17**, an uncompressed prosthetic valve **900,600,300** is shown in position within a heart **1750**. In particular, the valve **900,600,300** is inserted within a vessel **1460**, such as the aorta. Once inserted, the prosthetic valve **900.600,300** will passively open and close to control the flow of oxygenated blood through the left side of the heart and into the aorta for distribution to the body. Specifically, when the pressure in the left ventricle rises above the pressure in the aorta, the valve **900,600,300** opens, allowing blood to exit the left ventricle into the aorta.

Conclusion

[0130] While this specification includes many specifics, these should not be construed as limitations on the scope of the disclosure or of what may be claimed, but rather as descriptions of features specific to particular implementations of the disclosure. Certain features that are described in this specification in the context of separate implementations may also be implemented in combination in a single implementation. Conversely, various features that are described in the context of a single implementation may also be implemented in multiple implementations, separately or in sub-combination. Moreover, although features may be described above as acting in certain combinations and even initially claimed as such, one or more features from a claimed combination may in some cases be excised from the combination, and the claimed combination may be directed to a sub-combination or variations of a sub-combination. All of these embodiments are intended to be within the scope of the invention herein disclosed. These and other embodiments of the

present invention will become readily apparent to those skilled in the art after reading the detailed description of the embodiments of the invention having reference to the attached figures, the invention not being limited to any particular preferred embodiment(s) disclosed since various other modifications may occur to those ordinarily skilled in the art. Accordingly, the claimed invention is limited only by claims that follow below.

1. An apparatus comprising:
an isotropic filter screen formed of monofilament strands of biocompatible material that is porous to a body fluid;
the isotropic filter screen is flexible to flex back and forth between a concave and a convex condition; and
the isotropic filter screen is cut into a shape of one or more prosthetic valve leaflets each having at least one sealed edge.

2. The apparatus of claim **1**, wherein
the biocompatible material is one of monofilament polyester, monofilament polypropylene, monofilament acetyl-polymer, silk, or spider web.

3. The apparatus of claim **1**, wherein
a thickness of the isotropic filter screen and the one or more prosthetic valve leaflets is between one-hundredth and one-tenth of a millimeter.

4. The apparatus of claim **1**, wherein
the monofilament strands of biocompatible material are woven or knitted together to form the isotropic filter screen with a uniform pore size.

5. The apparatus of claim **1**, wherein
the isotropic filter screen is porous to blood, and
a pore size of openings in the isotropic filter screen and the one or more prosthetic valve leaflets is inclusively between fifteen and sixty microns.

6. The apparatus of claim **1**, wherein
the isotropic filter screen is cut with a non-contact cutting device to form the one or more prosthetic valve leaflets with at least one sealed edge without extended strands to prevent unraveling.

7. The apparatus of claim **6**, wherein
the non-contact cutting device is a laser.

8. The apparatus of claim **1**, wherein
the isotropic filter screen is cut with a heated contact cutting device to form the one or more prosthetic valve leaflets with at least one sealed edge without extended strands to prevent unraveling.

9. The apparatus of claim **8**, wherein
the heated contact cutting device is a radio-frequency or ultrasonic cutting device.

10. The apparatus of claim **1**, wherein
the one or more prosthetic valve leaflets are sterilized by gamma radiation, e-beam, ethylene oxide (EtO), heat, or chemical sterilization.

11. The apparatus of claim **1**, wherein
the one or more prosthetic valve leaflets are collapsed to a diameter of less than or equal to twenty-nine french (f).

12. The apparatus of claim **11**, wherein
the one or more collapsed prosthetic valve leaflets are sterilized by gamma radiation, e-beam, ethylene oxide (EtO), heat, or chemical sterilization.

13. The apparatus of claim **1**, wherein
the isotropic filter screen is cut into the shape of the one or more prosthetic valve leaflets such that each of the one or more prosthetic valve leaflets includes
an out-flow edge,
an in-flow edge, and
a pair of side edges.

14. The apparatus of claim **13**, wherein
each of the one or more prosthetic valve leaflets further includes
a pair of tab portions respectively extending outwardly beyond the pair of side edges and adjacent the out-flow edge, the pair of tab portions adapted to couple to a supporting structure to support the prosthetic valve leaflet.

15-64. (canceled)

65. An apparatus for checking back flow of a fluid in a tubular-like shaped vessel, the apparatus comprising:
a prosthetic valve leaflet formed from an isotropic screen material, the isotropic screen material having
pores with a pore size inclusively between fifteen microns and sixty microns, and
a thickness inclusively between one-hundredth of a millimeter and one-tenth of a millimeter.

66. The apparatus of claim **65**, wherein
the prosthetic valve leaflet is formed with one or more sealed edges so that it can be handled without coming apart.

67. The apparatus of claim **65**, wherein
the isotropic screen material is a monofilament polyester or polypropylene to form an isotropic structure with uniform pore size.

68. The apparatus of claim **66**, wherein
the shape of the prosthetic valve leaflet is cut from the isotropic screen material using a laser or other non-contact method to form the one or more sealed edges.

69. The apparatus of claim **65**, further comprising:
a support structure coupled to the prosthetic valve leaflet to support the leaflet between a first commissure portion and a second commissure portion of the support structure to form a prosthetic valve.

70. The apparatus of claim **65**, wherein
two or more prosthetic valve leaflets are coupled together to form a prosthetic valve.

71. The apparatus of claim **70**, further comprising:
a support structure coupled to the two or more prosthetic valve leaflets, the support structure to support the two or more prosthetic valve leaflets between a first commissure portion and a second commissure portion.

72. The apparatus of claim **71**, wherein
a contact length at outflow edges between the two or more prosthetic valve leaflets (a depth of coaptation) is inclusively between three millimeters and nine millimeters.

73. The apparatus of claim **65**, wherein
the isotropic screen material is formed by weaving or knitting a mono-filament polyester or mono-filament polypropylene.

74. The apparatus of claim **69**, wherein
the prosthetic valve is collapsed to a diameter less than or equal to twenty-nine French (nine and seven-tenths millimeter) to form a collapsed prosthetic valve.

75. The apparatus of claim **69**, wherein
the prosthetic valve is sterilized by gamma radiation, e-beam, ethylene oxide (EtO), heat (e.g., autoclave), or chemical sterilization.

76. The apparatus of claim **74**, wherein

the collapsed prosthetic valve is sterilized by gamma radiation, e-beam, ethylene oxide (EtO), heat (e.g., autoclave), or chemical sterilization.

77. The apparatus of claim **74**, wherein

the collapsed prosthetic valve is sterilized and stored in a storage container in a dry state such that it can be implanted into a mammal without rinsing.

78. The apparatus of claim **65**, wherein

the isotropic screen material is formed out of an acetylpolymer.

79. The apparatus of claim **65**, wherein

the isotropic screen material is formed out of silk.

80. The apparatus of claim **65**, wherein

the isotropic screen material is formed out of a spider web.

81-105. (canceled)

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